PMI TECHNICAL GUIDANCE
FY 2024

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.

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VECTOR MONITORING AND CONTROL

New/Key Messages

In line with global guidance, PMI continues to support evidence-informed deployment of traditional and new vector control tools to achieve universal coverage with at least one intervention (ITNs or IRS), as well as Operational Research/Program Evaluations for new tools and/or approaches (e.g, LSM, housing modification).

If any questions arise, countries should reach out to their PMI VMCT Operational Lead and Entomology Lead for further support.

ITN Procurement: PMI partner countries should continue to transition to new types of ITNs (e.g., 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 currently procures four brands of PBO nets (Olyset Plus, PermaNet 3.0, Duranet Plus, and Veeralin) as well as one dual insecticide net (Interceptor G2). PMI does not currently procure Royal Guard.

ITN Durability Monitoring: PMI is currently supporting durability monitoring in a number of partner countries and ongoing activities should continue. However, with the revision of the WHO PQT Guideline for Prequalification Assessment of ITNs and its module on Post-Market activities, PMI is pausing support for the initiation of new durability monitoring activities until new guidance and tools for post-market activities are developed.

IRS Insecticide Procurement and Rotations: IRS insecticide 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 PQT listings in late 2021: 2GARD (considered equivalent to Fludora Fusion) and Klypson (considered equivalent to SumiShield). PMI piloted these new products in 2022 in Zambia and Madagascar to assess operationalization and 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.

Reactive IRS: To maximize available tools to countries approaching malaria elimination, PMI can support technical assistance for countries implementing reactive IRS in response to active foci as part of a malaria elimination strategy. Support for procurement of insecticides or direct implementation of reactive IRS can be supported under OR/PE, if it is a country priority and resources allow. Due to the complicated logistics and lengthy lead times, PMI policy of not supporting IRS for epidemic outbreaks remains in place.

***Anopheles stephensi*:** A new malaria vector to the African continent, *Anopheles stephensi*, was first reported from Djibouti in 2012 and has now been confirmed in Djibouti, Sudan, Somalia, Ethiopia, and Nigeria. As an emerging threat to malaria control and elimination, PMI's *Anopheles stephensi* Task Force has generated general guidance on surveillance and control for countries at risk of *An. stephensi* invasion. Vigilance in morphological and molecular identification of anomalous *Anopheles* is encouraged for early detection of the species. 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 PQT approved larvicides. Appropriate environmental compliance approvals are required prior to larviciding implementation.

Evidence-Based Deployment of Vector Control Interventions

Since 2000, the scale up of interventions for malaria control including vector control and improved case management has led to dramatic reductions in the malaria burden in Africa with prevalence declining by 50% and the incidence of clinical disease by 40%. Much of the decline has been attributed to the scale up of vector control, with insecticide treated nets (ITNs) and indoor residual spraying (IRS) estimated to account for 68% and 13%, respectively, of the cases averted[1]. 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. Vector control currently accounts for a major share of PMI's budget.

In line with global guidance, including the World Health Organization (WHO) Guidelines for Malaria Vector Control (2019), PMI continues to support evidence-informed deployment of proven vector control tools to achieve universal coverage with at least one intervention (ITNs or IRS) to ensure effective vector control, as well as Operational Research/Program Evaluations for new tools and/or approaches. As per the October 2019 WHO Malaria Policy Advisory Committee (MPAC) meeting

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

report, "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. 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. Entomological data should be used to guide the selection and monitoring of vector control interventions, and should be based on insecticide resistance and vector bionomics data as well as other factors including community acceptance, cost, and national strategy/policies. Please see the **Entomological Monitoring** chapter for more information.

Two of PMI's main interventions – ITNs and IRS – aim to limit biting and reduce adult mosquito longevity, 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 ITNs and IRS through integrated vector management (IVM) strategies to provide effective vector control in the face of emerging insecticide resistance. 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.

New Tools and Operational Research for Vector Control

Other vector control technologies being considered or developed for routine use, but are not yet widely deployed, include larval source management, treated clothing and housing materials, attractive targeted sugar baits (ATSBs), eave tubes and ribbons, house screening/modification, population-wide deployment of ivermectin drug treatment, topical and spatial repellents, and genetically modified mosquitoes. In certain settings, PMI supports implementation of Larval Source Management (LSM) (in elimination settings or areas where *An. stephensi* has been detected) and procurement and/or deployment of topical repellents (in elimination settings) without the requirement for OR/PE. In other settings MOP-funded OR/PE may be used to assess LSM, topical repellents, house screening with untreated materials, insecticide-treated clothing, or spatial repellents.

At this time, PMI does not currently recommend or support MOP-funded implementation or OR/PE related to new tools under development (i.e., ATSBs, ivermectin, genetically modified mosquitoes) or

other vector control interventions (i.e., space spraying) for which there is no evidence to support a recommendation for malaria control. Should any of these 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. New tools are currently under review by the WHO Vector Control Advisory Group (VCAG) and the Innovative Vector Control Consortium. For further questions pertaining to PMI's support of new vector control tools, contact the VMCT **New Tools Teamlet.**

Larval Source Management

In some circumstances (e.g., detection of *Anopheles stephensi*, elimination settings), supplemental interventions that reduce adult mosquito abundance via destruction of larval habitats or application of larvicides (collectively termed Larval Source Management, or LSM) may be indicated. LSM, which involves the destruction of larval habitats via draining or filling or through the application of larvicides, has historically been successful in the United States, Europe, Brazil, Africa, and Southeast Asia. Modern randomized controlled trials are few, but those that exist indicate that LSM may reduce malaria transmission, but the certainty of evidence was low and applied only to areas where habitats were not extensive (<1 km^2)[2,3,4]. Given concerns about the feasibility of LSM, it is recommended in the WHO Guidelines for Malaria as a supplemental intervention to either ITNs or IRS in settings where larval habitats are "few, fixed, and findable", such as urban areas of arid regions. LSM is only indicated when coverage and quality of ITNs or IRS is high, but malaria transmission remains. Therefore, 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% coverage at the household level) is in place, and it is coupled with high quality case management and case investigation in transmission foci.

(2) **LSM OR/PE in higher transmission settings:** To support partner 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

[2] Choi L, Majambere S, Wilson AL. Larviciding to prevent malaria transmission. Cochrane Database Syst Rev. 2019 Aug 14;8(8):CD012736. doi: 10.1002/14651858.CD012736.pub2. PMID: 31425624; PMCID: PMC6699674.

[3] Newman RD, Mnzava A, Szilagyi Z. Mosquito larval source management: evaluating evidence in the context of practice and policy. Cochrane Database Syst Rev. 2013 Aug 29;(8):ED000066. doi: 10.1002/14651858.ED000066. PMID: 24156097.

[4] Tusting LS, Thwing J, Sinclair D, Fillinger U, Gimnig J, Bonner KE, Bottomley C, Lindsay SW. Mosquito larval source management for controlling malaria. Cochrane Database Syst Rev. 2013 Aug 29;2013(8):CD008923. doi: 10.1002/14651858.CD008923.pub2. PMID: 23986463; PMCID: PMC4669681.

quality coverage of ITNs or IRS, and/or other malaria interventions (not necessarily limited to vector control interventions; e.g., SMC), in order to generate the evidence needed to develop more comprehensive guidance on LSM.

(3) **Larvicide implementation with entomological monitoring in areas where *Anopheles stephensi* is present** (i.e., Ethiopia and Nigeria presently). As *An. stephensi* uses larval sites such as water storage tankers, concrete cisterns, 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 PQT approved larvicides. Appropriate environmental compliance approvals are required prior to larviciding implementation. See ***Anopheles stephensi* section** below for additional guidance.

See the **SBC Section** for guidance on OR/PE related to LSM messaging to communities.

Topical Repellents for Elimination Settings

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. PMI support for the procurement and/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. Please see the **Elimination and Supply Chain** chapters of the guidance for more information.

Housing Screening

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.

ENTOMOLOGICAL MONITORING

Introduction

To ensure appropriate selection of and maximum benefit from vector control interventions, PMI supports entomological monitoring, which is the backbone of an IVM strategy, in all focus countries. The large investments in ITNs and IRS made by the Global Fund, PMI, and other donors, and our dependence on a limited number of classes of insecticides make it imperative that national programs monitor and evaluate entomological parameters. The overall aim of entomological monitoring is to answer specific questions to inform programmatic decision making. Longitudinal entomological monitoring is encouraged, but it should not be a static process. Each year programs should strive to answer certain questions and raise new ones, and this should be done within a broader context, considering how best to complement collection of other types of malaria data. 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 interventions which exploit vector behaviors, as well as to evaluate their quality and impact.
3. **Quality and performance assessments of IRS** to determine insecticide residual efficacy and spray quality. Please see the ITN Chapter for updates to guidance on ITN durability monitoring.
4. **Maintenance of well-characterized mosquito colonies**, including susceptible, and where possible, resistant strains derived from local populations, to enable insecticide susceptibility testing and quality/performance assessments of vector control interventions.

Insecticide Resistance Monitoring

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

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

The concept is simple, though the details can be complex: match insecticides delivered (whether via 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 VMCT to design a useful and cost-effective sampling scheme** that meets the needs and answers the questions of the national program and ensures representative vector populations are sampled across space and time. Once monitoring sites are established, baseline insecticide susceptibilities should be determined before interventions are implemented.

Prioritization of insecticides for testing

Currently, products from six classes of insecticides with WHO PQT approval are available for use in adult malaria vector control with ITNs and/or IRS: carbamates, neonicotinoids, organophosphates, pyrethroids (alone or in combination with the synergist piperonyl butoxide (PBO)), pyrroles, and insect growth regulators (IGRs). Ideally, susceptibility testing should be done for the full range of insecticides; however, 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. These data can provide immediately actionable information, and a profile of historical insecticide resistance in the vector populations. 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 (pirimiphos-methyl, an organophosphate), SumiShield 50 WG (clothianidin, a neonicotinoid), and Fludora Fusion (clothianidin, a neonicotinoid, in a mixture with deltamethrin, a pyrethroid). PMI is also currently piloting 2GARD and Klypson, equivalents of SumiShield 50 WG and Fludora Fusion, respectively, that recently received WHO PQT approval. WHO PQT approval of four additional products for IRS is anticipated in the near future: Imergard (perlite, a mechanical insecticide), Pirikool 300 CS (pirimiphos-methyl, an organophosphate), Sylando (chlorfenapyr, a pyrrole) and Vectron T500 (broflanilide, a meta-diamide). 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) – protocol currently under validation

Testing for carbamates (bendiocarb) or DDT is only recommended if these insecticides are currently being used or are under consideration for use. Note that currently no organochlorine (i.e., DDT) products have a WHO PQT listing, but DDT may still be procured and deployed in some countries. Currently there is no protocol for susceptibility testing for perlite, but PMI will work with the manufacturer and other stakeholders to develop and validate a protocol if and when a WHO PQT product becomes available. 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. Testing for pyriproxyfen is only recommended if ITNs with this insecticide are currently deployed or are under consideration for deployment. While there is a single dual AI ITN containing pyriproxyfen with a WHO PQT listing (Royal Guard), it is not currently recommended for procurement. Therefore, PMI currently recommends insecticide susceptibility testing with the active ingredients of these products:

1. Deltamethrin +/- PBO
2. Permethrin +/- PBO
3. Alpha cypermethrin +/- 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 or dual active ingredient-AI ITNs) if resistance is detected at the diagnostic dose (see section on Insecticide resistance intensity testing 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.

Further background information on insecticides used in vector control for public health, including their safety and efficacy, can be found at the WHO PQT website.[5] An excellent resource for learning more about the modes of action is the Insecticide Resistance Action Committee.[6]

Testing methods and interpretation of results

Mosquitoes should ideally be collected as larvae and reared to the adult stage before testing. However, this is not always feasible and collection of eggs from wild caught gravid or blood fed females may be reared to the adult stage for testing. Where this is not possible, direct testing of wild caught females may be done. Whichever approach is used, effort should be made to sample distinct vector populations to ensure susceptibility representation from across the site and not just one population. Susceptibility tests should be conducted and results interpreted according to the most recent versions of testing protocols as published in the WHO Manual for Monitoring Insecticide Resistance in Mosquito Vectors and Selecting Appropriate Interventions. Ensure that susceptibility tests are done according to the most recent versions of testing protocols.

Molecular markers of insecticide resistance

[5] https://www.who.int/pq-vector-control/en/

[6] http://www.irac-online.org/

Current molecular markers of insecticide resistance are limited to target site mutations, including *kdr* for pyrethroids and organochlorines or *ace-1* for organophosphates and carbamates, which can be detected by PCR and a number of genes related to metabolic resistance and cuticular thickening. Resistance is highly variable depending on ecological context, vector diversity, vector control tools in use, and other factors. Therefore, the use of *kdr* as a marker of insecticide resistance should be tailored accordingly. Generally, *kdr* assays should only be performed on mosquitoes that have been found to be resistant to pyrethroids through bioassays and only conducted every other year. PCR detection of *ace-1* should be performed on previously bioassayed samples every year. Metabolic resistance can be detected by using bottle assays or biochemical assays with synergists such as PBO, or certain molecular assays. If metabolic testing is possible, that is highly encouraged. As new markers are discovered and/or new assays are developed, the VMCT will develop new guidance and roll out appropriate protocols. For more information and to develop a country specific plan, contact the **VMCT Laboratory Teamlet.**)[7] [8] [9].

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. Discussions are underway to shape the PMI-supported Enhanced Detection of Insecticide Resistance (PEDIR) program which will support local scientists training in advanced or new molecular methods for insecticide resistance monitoring. More information will be shared as it is available.

Standard operating procedures (SOPs)[10] for all insecticide resistance monitoring methods are available through VMCT.

[7] 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.

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

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

[10] https://pmivectorlink.org/resources/tools-and-innovations/

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 communities 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 should be based on the question(s) being answered. In some settings, building in-country entomological monitoring expertise and expanding public health entomology capacity 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.

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 trap collections. Larval collections may also be conducted, particularly in cases where there may be significant outdoor feeding.

2. **Indoor and outdoor human biting rates.** Indoor and outdoor human biting rates, defined as the number of mosquito bites per person per unit time, should be determined nightly and/or hourly to understand where and when transmission is most likely occurring. HLCs are the preferred method, and are typically conducted overnight from 6:00 pm to 6:00 am, but may be extended earlier and/or later 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. See section below on "Alternatives to Human Landing Catches" below for additional information. CDC light traps hung next to a person sleeping under an ITN may be used to provide some indication of the rates of indoor feeding, but not on the relative importance of outdoor transmission.

3. **Indoor and outdoor resting densities.** Indoor and outdoor resting densities, defined as the number of mosquitoes collected per house/shelter per day, should be determined to assess the suitability or evaluate the impact of indoor interventions, particularly IRS. Resting collections should take place early in the morning (prior to 8 am) before mosquitoes exit houses or outdoor resting locations. Indoor resting densities may be determined from pyrethrum spray collections or Prokopak aspirations while outdoor resting densities may be determined using pit traps or clay pots. It should be noted that in homes with complete ITN or IRS coverage, indoor

resting densities may be extremely low. In this case, PMI Entomology backstops should be consulted on best actions to take.

4. **Sporozoite rates.** Mosquito infectivity is determined by measuring the sporozoite rate, which is the proportion of mosquitoes in a population harboring infective sporozoites in their salivary glands. The sporozoite rate is necessary to determine the entomological inoculation rate (EIR), which is a measure of transmission intensity. It is also useful in detecting differences in infectivity between insecticide susceptible and resistant vectors, which may be an indication of control failure. In areas where species composition is changing, measuring sporozoite rates may be critical to determine vector status of new or secondary vectors. Sporozoite-positive mosquitoes are identified by enzyme-linked immunosorbent assay (ELISA)[11], bead assays, or PCR. Because PCR does not distinguish sporozoite-stage (infectious) parasites from other stages in the mosquito, parasite PCR should only be used to determine the presence of parasites, but is not recommended as a method to determine infectivity[12]. It should also be noted that as mosquito populations are reduced, it can become increasingly difficult to collect sufficient mosquitoes to test and this small sample size may not produce a reliable estimate of the sporozoite rate.

5. **Entomological inoculation rate (EIR).** The EIR is a measure of malaria transmission intensity that describes the number of infectious bites an individual is exposed to in a given time period (typically a year or transmission season), and is estimated from human biting rates (generally determined by HLCs) and sporozoite rates. 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 and EIR estimates should be reported alongside information on geography, season, and other relevant ecosystem characteristics which may influence this metric.

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 ELISA or PCR. Estimates of host feeding rates are strongly affected by host availability and sampling strategy and

[11] http://www.mr4.org/Portals/3/Pdfs/Anopheles/3.3%20Plasmodium%20Sporozoite%20ELISA%20v%201.pdf)

[12] Hendershot, A.L., Esayas, E., Sutcliffe, A.C. *et al.* A comparison of PCR and ELISA methods to detect different stages of *Plasmodium vivax* in *Anopheles arabiensis*. *Parasites Vectors* **14**, 473 (2021). https://doi.org/10.1186/s13071-021-04976-z

should therefore be interpreted with caution, and any such estimates should be reported with relevant contextual information.

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 shorten 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., control versus intervention) or trend over time. 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. Collecting human behavior observation (HBO) data in relation to malaria vector behavior data can help answer two main questions:
    a. How does human behavior impact ITN or IRS effectiveness based on indoor vector exposure?
    b. Do gaps in protection exist due to outdoor human and vector behavior?

    To provide more detailed context and estimates on human-adjusted hourly biting rates, direct observational data 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 human biting rates in the same location (for example, 6:00 pm to 6:00 am or extended depending on local vector behavior). It is often the HLC collector or HLC supervisor who documents HBOs. In the event that HBO data cannot be collected because direct observation

of household inhabitants is not possible or if the sample size is too small, then a survey based approach could be considered, although not preferred. Household surveys such as the malaria indicator survey (MIS) or the malaria behavior survey (MBS) have the potential to capture human behavior data with limited additional cost. However, consideration should be given to the use of self-reports in the MBS and MIS and the extent of geographical and temporal overlap between these surveys and entomological monitoring surveys.[13] The VMCT will work with the SBC team to identify the optimal approach to measure human behavior across different countries. The VMCT and SBC teams will also work to triangulate data that is collected by surveys (e.g., MIS and MBS) versus direct observations.

The SOP and data collection form are available from the VMCT. A survey form is also available if this pathway of data collection is chosen.

For additional information on mosquito collection techniques, see WHO's comprehensive *Manual on Practical Entomology for Malaria Control* *Part 1* *and* *Part 2* and *Training Manual on Malaria Entomology for Entomology and Vector Control Technician*. Training videos are also available for a number of mosquito collection methods at https://vimeo.com/ivmproject.

Standard operating procedures (SOPs)[14] for all vector bionomics monitoring methods are available and can be obtained**.** 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[15]. 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

[13] Monroe, April, et al. "Methods and indicators for measuring patterns of human exposure to malaria vectors." *Malaria journal* 19.1 (2020): 1-14.

[14] https://pmivectorlink.org/resources/tools-and-innovations/

[15] 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

fever). Whether there is additional risk for these diseases is not known. At present, guidance from PMI is that HLCs may continue, if supported by national ethics committees and National Malaria Control Programs. Should evidence emerge that collectors are at increased risk compared to non-collectors, this guidance will be revised.

Alternative trapping methods 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[16].

Mosquito identification

Accurate mosquito species identification underpins all entomological indicators for malaria. As the major vectors of malaria in Africa are members of species complexes, whereby different species are morphologically identical but genetically distinct (e.g., *Anopheles gambiae s.s., An. arabiensis,* and *An. coluzzii*), samples morphologically identified as vectors where a species-specific PCR assay is available 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 PCR assays routinely fail to amplify DNA, and potential laboratory issues have been addressed, this may be a sign of incorrect initial morphological identification. DNA sequencing of cytochrome c oxidase subunit 1 gene from the mitochondrial genome (CO1) or the internal transcribed spacer 2 region from the nuclear ribosomal DNA (ITS2) targets may help resolve the questions surrounding the identity of the species, but it should be noted that there is not yet a complete understanding of how existing species and DNA sequences correspond.

Programs should work towards maximizing the number of vector mosquito samples that are processed for molecular analysis; however, if all samples cannot be analyzed, a subsample should be tested, with the number of specimens in this subsample determined by the relative abundance of the sibling species, the capacity of the reference laboratory, and the purpose of the molecular identification tests. It is recommended that samples analyzed for parity, sporozoite infection, blood meal source, or molecular markers of insecticide resistance also be identified to the species level using molecular assays. A

[16] Briët, O.J.T., Huho, B.J., Gimnig, J.E. et al. Applications and limitations of Centers for Disease Control and Prevention miniature light traps for measuring biting densities of African malaria vector populations: a pooled-analysis of 13 comparisons with human landing catches. Malar J 14, 247 (2015). https://doi.org/10.1186/s12936-015-0761-9

laboratory workflow chart, as well as a workflow for non-amplifications, is available from the VMCT **Laboratory Teamlet**.

It should be noted that as vector control efforts have progressed and certain targeted and susceptible malaria vector populations have been markedly reduced, 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 individuals identifying mosquitoes should be offered refresher training and tested frequently.

An invasive malaria vector, *An. stephensi*, has established populations in the Horn of Africa and the current extent of its distribution on the African continent is unknown. From PMI focus countries, there are known populations in Ethiopia and Nigeria; neighboring PMI countries and other countries 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. Images of the differences between these species can be seen in the 2019 WHO VectorAlert: *Anopheles stephensi* invasion and spread [17] and pinned specimens may be requested. For additional information, see section on *Anopheles 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[18]. IRS programs operating under PMI's central mechanism implement clear protocols to ensure the quality of IRS, including robust training of spray operators, supervisors, and all relevant spray personnel, and "directly observed spraying" whereby supervisors are required to observe spray operators' technique while spraying houses and to provide on-the-spot correction as needed. Guidelines for IRS management and supervision checklists are available on the PMI website.

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

[17] https://apps.who.int/iris/rest/bitstreams/1242915/retrieve

[18] IRAC (2011) Prevention and Management of Insecticide Resistance in Vectors of Public Health Importance https://irac-online.org/documents/irm-vector-manual/?ext=pdf

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. For formulations that include a mixture of active ingredients including a pyrethroid and a non-pyrethroid, it is necessary to identify a pyrethroid resistant strain to assess the residual activity of the non-pyrethroid insecticide. If these are not available, wild-caught, unfed, female mosquitoes can be used as long as there is no demonstrated resistance to the non-pyrethroid insecticide 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 control mortality is >20% on a given day. However, this requirement may be relaxed for mortality assessments that continue beyond 5 days after exposure, as may be the case for clothianidin assays.

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

Standard operating procedures (SOPs)[19] for IRS quality assurance and residual efficacy monitoring methods are available.

Initial spray quality and monthly residual efficacy data, which is available in real time via VectorLink Collect, should be shared with the NMP, implementing partners, and PMI as soon as results are available

[19] https://pmivectorlink.org/resources/tools-and-innovations/

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.

Bioefficacy Monitoring and Chemical Analysis of ITNs

Monitoring the insecticidal activity and insecticide content of ITNs is important to help ensure ITN quality . 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 be used, though resistant strains are needed to evaluate PBO synergist and dual insecticide ITNs. This activity requires specialized facilities and staff, in particular an insectary with a validated 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.

If durability monitoring is conducted, PMI recommends only conducting bioassay and chemical content testing of 30 nets (instead of 45 nets) at three timepoints (12, 24, and 36 months; "baseline"/1-6 months activities are no longer required). Guidance with respect to pre-distribution testing is: *20 ITNs per site/brand will be sampled from the central stores to undergo bioassay and chemical residue testing. 10 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 available at https://www.durabilitymonitoring.org/. See SOPs[20] for the laboratory and semi-field testing of PBO and dual AI ITN products here: https://innovationtoimpact.org/workstreams/standard-operating-procedures/

Measurement of insecticidal content 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 ITNs made of polyethylene with insecticide directly incorporated into the fiber.

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 (ie., deltamethrin), and/or new insecticides for

[20] Lees, R et al. Strain Characterisation for Measuring Bioefficacy of ITNs Treated with Two Active Ingredients (Dual-AI ITNs): Developing a Robust Protocol by Building Consensus. Insects 2022, 13(5), 434; https://doi.org/10.3390/insects13050434

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 pyrethroid susceptible strain and a pyrethroid 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 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.

Maintenance and Characterization of Mosquito Colonies

Susceptible colonies of mosquitoes are used for the assessment of ITNs, quality control of IRS, and verification of treated papers for WHO susceptibility tests and CDC bottle bioassays. Susceptible colonies should be tested quarterly in order to ensure that these established colonies have not been contaminated by resistant colonies kept in the insectary, or wild mosquitoes entering the insectary. Insectary layout should also consider the location of insecticide susceptibility testing rooms to ensure that these are separated from rearing rooms for susceptible strains. 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 PCR assays 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. For further guidance see the section on **Molecular Markers of Insecticide Resistance**.

As countries are encouraged to keep locally derived pyrethroid-resistant strains of *Anopheles* for testing the efficacy of PBO or dual insecticide nets, these must also be regularly selected with a pyrethroid and characterized, both phenotypically and genotypically 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 partner 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 malaria operational plans (MOPs), though certain limited 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 use a centralized database developed on the DHIS-2 platform, known as VectorLink Collect, and corresponding mobile data collection app. 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. NMPs and government counterparts also have access to this system to allow for country ownership of vector control data. Currently, the VectorLink Collect Entomology module consists of data collection programs focusing on insecticide resistance, insecticide residual life and vector abundance and behavior data. A laboratory module is under

development and expected to be rolled out over the next 12 months. 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 and IRS residual efficacy data will be available to NMPs 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 9 months prior to the next spray campaign to allow for insecticide resistance data evaluation that will inform timely insecticide and ITN procurement, given lead times for nets can be more than 12 months.**

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 VMCT.

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 508 compliant annual entomology reports online for public access once approved by the Mission Activity Manager and PMI HQ COR. Reports should be provided to Missions, PMI headquarters (including Entomology and Operational Leads), and NMPs. The VMCT recommends that bilateral projects follow similar reporting guidelines and frequencies. PMI country teams should ensure that the PMI HQ Entomology and Operational Leads receive all relevant reports from bilateral vector control partners. Missions are encouraged to support NMPs and/or National Vector Control Working Groups to review entomological data/reports along with epidemiological data/reports (obtained from HMIS) to inform vector control decision making.

Anopheles stephensi, an invasive malaria vector in Africa

In 2012, *Anopheles stephensi,* a primary malaria vector in south Asia and the Arabian Peninsula, was detected in a seaport in Djibouti. Djibouti approached pre-elimination with <2000 cases of malaria per year prior to the detection of *An. stephensi*, however, by 2020 cases of malaria increased 36-fold and suspect cases increased from 100,000 to over 300,000 between 2018 and 2020 alone. In 2016, *An. stephensi* was detected in Ethiopia and Sudan, Somalia in 2019, and Nigeria in 2020.

This mosquito vector can thrive in both urban and rural environments. Where established, the vector is most often found in artificial containers such as wells, water storage tankers, and concrete cisterns, as well as smaller containers and natural habitats. By using artificial containers as larval habitats, *An. stephensi* can persist year round, threatening to alter the malaria landscape and seasonal targeted interventions. For example, in Ethiopia in 2022, an outbreak of malaria occurred during the dry season

in the urban area of Dire Dawa, and this outbreak was directly linked to *An. stephensi* [21]. Further invasion of this mosquito vector on the African continent has potential to put an additional 126 million people at risk of malaria each year based on modeling estimates[22], therefore, early detection and rapid response strategies are necessary.

Currently, there are two PMI countries, Ethiopia and Nigeria, where there is a confirmed presence of *An. stephensi*. Neighboring countries, those with high influx of trade traffic through major ports, and those with suitable habitats for population establishment should be considered high risk;however, all PMI countries in Africa should be vigilant for this vector.

PMI action plan to respond to An. stephensi

A PMI *Anopheles stephensi* Task Force was established in 2021 with representatives from technical areas including: SBC, OR, elimination, case management, SI, VMCT, and the PMI Ethiopia, Nigeria and Kenya country teams. An Action Plan document has been developed which provides additional information on specific activities, SOPs, and research needs. . Given limited data at this time about the extent of the distribution of *An. stephensi* in Africa, the Task Force, in alignment with the 2022 WHO initiative and WHO Global framework for the response to malaria in urban areas has decided to frame its approach as **mitigation** of the harmful effects of *An. stephensi* utilizing **enhanced** vector and disease **surveillance, coordinated intervention implementation,** and **close monitoring**. This approach and action plan 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 ports and seaports with connectivity to major transport/commerce routes. In Ethiopia, invasive *An. Stephensi* larval 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 PMI activity for most countries, it will likely require additional investment, thus coordination with existing vector surveillance programs, particularly *Aedes* programs, may be an efficient way to leverage existing infrastructure for *An. stephensi* surveillance. The following PMI focus countries are part of the West African *Aedes* Surveillance Network (WAASuN): Benin, Côte d'Ivoire, Ghana, SenegalGuinea, Liberia, Mali, Sierra Leone, and Nigeria, where *An. stephensi* has been detected.

Adult *An. stephensi* may be misidentified morphologically as *An. gambiae* s.l. if the correct morphological key is not used. The updated Coetzee 2020 key[23], which includes *An. stephensi*, should be used for

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[21] Emiru T, et al. *Anopheles stephensi* is linked with a recent outbreak of malaria in Dire Dawa City, Ethiopia. *American Society of Tropical Medicine and Hygiene Annual Meeting* 2022. LB-5187.

[22] Sinka ME, et al. A new malaria vector in Africa: Predicting the expansion range of *Anopheles stephensi* and identifying the urban populations at risk. Proc Natl Acad Sci U S A. 2020 Oct 6;117(40):24900-24908. doi: 10.1073/pnas.2003976117.

[23] Coetzee, M. 2020. Key to the females of Afrotropical *Anopheles* mosquitoes (Diptera: Culicidae). *Malaria Journal,* 19, 70. https://doi.org/10.1186/s12936-020-3144-9

[2] Strategies for conducting Anopheles stephensi surveys in non-endemic areas - ScienceDirect

morphological identification to ensure any suspected *An. stephensi* are appropriately identified. Pinned specimens of *An. stephensi* has been prepared at CDC and can be requested. Additional information on larval surveys can also be obtained. A new *An. stephensi* PCR method has been recently made available and should be considered as a possible confirmation tool for suspected *An. stephensi* samples[24]. For additional guidance or troubleshooting with this assay, contact the VMCT Laboratory Teamlet.

A relatively simple and cost-effective option to determine whether *An. Stephensi* is present in a country is to revisit mosquitoes collected through routine entomological surveillance or insecticide resistance monitoring (IRM). Specifically, mosquitoes that were collected from locations at high risk of *An. stephensi* establishment (maps provided in the PMI *An. stephensi* Action Plan) that did not amplify using species ID PCR or were noted to have unique morphology should be examined to determine if they are *An. stephensi*. Please reach out to the *An. stephensi* Task Force for additional information on approaches to confirm the presence of *An. stephensi* in the country.

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 NMPs. 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 and the urban populations impacted. Environmental compliance paperwork should be completed for WHO PQ-approved larvicides as soon as possible. Work with your Entomology Lead and Operational Lead to ensure that the appropriate environmental compliance approvals are in place for larviciding implementation.

Social Behavioral Change

Once a response to *An. stephensi* has been identified, SBC activities should be incorporated within that strategy to promote the interventions and associated individual, household, and community level behaviors that support the uptake and maintenance of interventions to combat invasive *An. stephensi*. Cross-cutting considerations for SBC strategies to address malaria transmitted by *An. stephensi* include:

1. Ensure target behaviors are feasible in terms of time, skills, and resources
2. Ensure SBC approaches meet the needs of target population(s) by considering
    a. Levels of literacy
    b. Local languages and cultural appropriateness

[24] Molecular diagnostics for early detection of invasion of malaria vector Anopheles stephensi | bioRxiv

    c. Appropriate channels, including informal communication channels, to reach higher risk and mobile populations, e.g., construction workers, miners, agricultural and daily or seasonal workers or those who frequently move between rural to peri-urban and urban areas. Contextually relevant higher risk groups should be identified in the target area and channels tailored accordingly.
3. Identify and engage contextually relevant community leaders and community-based civil society organizations early in the process. This may include spiritual leaders, faith-based organizations, trade unions, rotary groups, scout groups, and others
4. Promote multi-sectoral collaborations such as municipal, transportation/commerce, education, and employer-based programs to increase engagement and promote target behaviors
5. Promote collaborations across malaria partners for a comprehensive malaria response (e.g., service delivery, SBC, vector control)
6. Tailor SBC activities and message framing to communicate in accordance with the level of *An. stephensi* risk

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 guidance is expected to be available for dissemination in early CY2023 The findings from this activity will be used to help further inform a comprehensive strategy for response to this vector and will be incorporated into the Action Plan.

Surveillance Monitoring and Evaluation

Anopheles 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. Monitoring of malaria trends in urban and peri-urban environments is recommended to monitor for case 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. *Anopheles stephensi* may also persist during dry periods when other vectors do not, so monitoring malaria case data for increases in urban areas during dry periods is recommended.

In areas where *An. stephensi* has been detected, monitoring case data at the most focal level possible may be warranted. 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 detailed guidance can be found in the PMI *An. stephensi* Action Plan. For further questions, contact the **PMI *An. stephensi* Task Force.**

INSECTICIDE-TREATED NETS

Introduction

Insecticide-treated nets are a core intervention for malaria control and have contributed greatly to the dramatic decline in disease incidence and malaria-related deaths seen since 2000. They are proven to be effective at reducing child mortality, parasite prevalence, and uncomplicated and severe malaria episodes.[25] Parasite prevalence in endemic sub-Saharan Africa decreased by 50% between 2001 and 2015, with 68% of this decline attributed to the use of ITNs.[26] More than 2.7 billion ITNs have been delivered since 2004 in malaria endemic countries.[27] By 2021, 68% of households in sub-Saharan Africa had at least one ITN, increasing from about 5% in 2000. The percentage of households owning at least one ITN for every two people increased from 1% in 2000 to 38% in 2021. In the same period, the percentage of the population with access to an ITN within their household increased from 3% to 54%. The percentage of the population sleeping under an ITN also increased between 2000 and 2020 for the whole population (from 2% to 47%). However, since 2017, overall access to and use of ITNs has continued to decline in sub-Saharan Africa.[28]

To achieve and maintain ITN coverage, countries should apply a combination of mass net distribution through campaigns and continuous distribution through multiple channels, through antenatal care (ANC) clinics and the expanded programme 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 to sustain coverage because coverage gaps can start to appear almost immediately post-campaign due to net deterioration, loss of nets, and population growth.[29] See ITN Distribution below.

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

[26] 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.

[27] https://allianceformalariaprevention.com/working-groups/net-mapping/

[28] WHO. World malaria report 2022.

[29] Ibid.

New Types of ITNs

Given the new types of nets now available in the context of pyrethroid resistance, some countries may deploy multiple types of nets. ITN strategies may be sub-nationally tailored, based on entomology, epidemiology, and other types of data. PMI partner countries are expected to select the most appropriate type(s) of nets given insecticide resistance and other factors. 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. In areas of pyrethroid resistance, PMI recommends deployment of piperonyl butoxide (PBO) or dual AI ITNs. Given current production constraints of dual AI nets, countries may need to prioritize PBO ITNs unless resistance data indicates that PBO does not restore susceptibility to pyrethroids. For more guidance on multi-product ITN distribution, refer to https://allianceformalariaprevention.com/tools-guidance/multi-product-itn-distribution/.

Piperonyl butoxide (PBO) nets: Piperonyl butoxide (PBO) is a synergist that, despite having no insecticidal activity on its own, enhances the potency of certain insecticides. PBO inhibits mixed function oxidase systems (MFOs, also known as cytochrome P450 mono-oxidases) of mosquitoes. 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. 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.

Dual-insecticide nets: These are ITNs that have two active ingredients. The only dual-insecticide nets currently available still contain a pyrethroid. Unlike PBO, which is a synergist that does not have intrinsic insecticidal activity, 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. The Interceptor G2 has a combination of alphacypermethrin, a pyrethroid, and chlorfenapyr, a slower-acting insecticide that targets energy production in the mitochondria. The Royal Guard has a combination of alphacypermethrin and pyriproxyfen, an insect growth regulator that reduces fecundity of female mosquitoes and may also reduce their blood feeding and longevity.

The WHO recognizes three classes of insecticide-treated nets:

1) ITNs designed to kill insecticide-susceptible mosquitoes with proven public health impact, which includes pyrethroid-only nets. This class of ITNs has a strong recommendation from WHO and has been implemented at-scale in malaria endemic countries.

2) ITNs designed to kill insecticide-resistant mosquitoes, which include ITNs with a non-pyrethroid insecticide (e.g., chlorfenapyr) or a pyrethroid insecticide and synergist, such as piperonyl butoxide (PBO). Pyrethroid-PBO nets prequalified by WHO are conditionally recommended in place of pyrethroid-only ITNs where principal malaria vectors exhibit intermediate levels of pyrethroid resistance, and where resistance is conferred at least in part by a monooxygenase-based resistance mechanism.
3) ITNs designed to sterilize or reduce their fecundity, which will likely include pyrethroid plus pyriproxyfen nets and the class will be created once the public health value of a first-in-class ITN product with insect growth regulator is demonstrated.[30]

Two trials have demonstrated improved efficacy of pyrethroid-PBO treated ITNs[31][32] and one trial demonstrated improved efficacy of a dual-insecticide ITN (pyriproxyfen and permethrin)[33]. Two dual-insecticide ITNs, the Interceptor G2[34] and Royal Guard[35], are listed by WHO PQ, though neither has yet received a WHO policy recommendation. A 2022 published study on dual active ingredient (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. The pyriproxyfen ITN reduced malaria prevalence at the 12-month follow up but the effect did not extend through the 24-month time point; the pyriproxyfen net did not have any effect on malaria incidence in either the first or second year of the study.[36] Results from the Benin trial were presented at ASTMH in Seattle in November 2022 and these largely confirmed the findings from Tanzania (publication forthcoming). Based on the trials in Uganda

[30] WHO Guidelines for malaria (June 2022). Accessed: https://www.who.int/publications/i/item/guidelines-for-malaria

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

[32] 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 long-lasting insecticidal nets with and without piperonyl butoxide on malaria indicators in Uganda (LLINEUP): a pragmatic, cluster-randomised trial embedded in a national LLIN distribution campaign. Lancet. 2020: 395:1292-1303.

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

[34] 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.

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

[36] Mosha JF, Kulkarni MA, Lukole, E, Matowo NS, Pitt C, Messenger LA, et al. 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. Lancet 2022: 399: 1227-1241, https://doi.org/10.1016/S0140-6736(21)02499-5

and Tanzania, VCAG concluded in areas where pyrethroid resistance is high, PBO-pyrethroid nets are more effective than those without PBO.[37] Results from the first epidemiological trial in Tanzania were reviewed in October 2021 where VCAG concluded Interceptor® G2 was more effective than the standard net, with the effect being stronger in the first year of the trial. Royal Guard® net did not demonstrate higher disease impact compared to the control net.[38] A formal policy recommendation has not been provided for the Interceptor G2 or the Royal Guard. Given supply constraints and cost, PMI may procure the Interceptor G2 in areas with high pyrethroid resistance that is not mitigated by PBO. PMI does not procure Royal Guard.

PMI ITN Procurement Policy

PMI's current ITN procurement policy requires that ITN products, at minimum, be on the WHO Prequalification Team (PQT) list of Prequalified Vector Control Products (see full list below) to be eligible for PMI procurement. 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. Once the new WHO Guideline for Prequalification Assessment of Insecticide Treated Net (ITNs) is finalized (expected by the end of CY 2022), PMI may revisit these additional criteria if the weight of evidence on effectiveness is sufficient for procurement decisions.

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[39], 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, and countries may select between pyrethroids based on insecticide susceptibility data.

[37] WHO. Fourteenth meeting of the WHO Vector Control Advisory Group: meeting report, 19-21 April 2021. 2021.
[38] WHO. Sixteenth meeting of the WHO Vector Control Advisory Group. Geneva: WHO; 2022.
[39] 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. https://www.mdpi.com/2075-4450/12/9/826

As of November 2022, WHO has provided a list of current prequalified long-lasting ITN products:[40]

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]*
- V.K.A Polymers: MAGNet *[Alpha-cypermethrin]*
- *Yorkool: Yorkool® *[Deltamethrin]*
- **NRS Moon Netting FZE: Tsara® [Deltamethrin]*
- *NRS Moon Netting FZE: Tsara Soft® *[Deltamethrin]*

PBO

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

Dual AI

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

(*) Denotes an ITN product not procured by PMI

[40] WHO Prequalified Vector Control Products (24 October 202209 November 2021) https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list

The following ITNs are currently under assessment by PQ; PMI will provide an update if they are approved and available for procurement by PMI:

- Shobikaa Impex Private Limited: Duranet Plus *2.0 [Alpha-cypermethrin; Piperonyl Butoxide]*
- Shobikaa Impex Private Limited: GreenNet *[Deltamethrin]*
- Vestergaard Frandsen S.A.: PermaNet Dual *[Chlorfenapyr, Deltamethrin]*
- Real Relief Health ApS, Reliefnet *[Deltamethrin]*
- Horison Textile Co., Ltd: VitalNet *[Alpha-cypermethrin]*
- Fujian Yamei Industry: Yahe 4.0 *[Alpha-cypermethrin; Piperonyl Butoxide]*
- Yorkool: Yorkool G3 LN *[Deltamethrin, Piperonyl Butoxide]*

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

New Nets Project and Net Transition Initiative

The New Nets Project (NNP) (2018-2022), is jointly funded by Unitaid and the Global Fund with additional support from the Bill and Melinda Gates Foundation and the President's Malaria Initiative. IVCC created a consortium of partners to ensure the rapid deployment of new dual-AI nets to a limited number of partner countries where a combination of randomized controlled trials in Benin and Tanzania, and effectiveness pilots in Burkina Faso, Rwanda, Mozambique, Nigeria, and Mali, seek to establish the impact and cost-effectiveness data needed for a World Health Organization (WHO) policy recommendation that would be required for scale-up. Interim results have been released for the New Nets project and were presented at ASTMH in November 2022.[41] The results suggest universal coverage campaigns with any of the new net types may be more effective than those using pyrethroid-only ITNs. The effect was less pronounced in the West African setting of Burkina Faso potentially due to complex resistance profiles. It will be important to consider additional epidemiological data as well as factors such as ITN access and use, durability, cost and cost effectiveness, and human behavior when evaluating the potential value of new nets across settings. Evidence from these pilot studies complements the cRCTs in Tanzania and Benin.

In addition, the Bill & Melinda Gates Foundation, in collaboration with MedAccess, entered into a volume guarantee agreement with BASF to offer reduced Interceptor G2 pricing for the effectiveness, as well as operational pilots. The NNP achieved its targeted price for IG2 nets and, therefore, any orders placed outside the project will benefit from this lower pricing. When freight, quality assurance and

[41] New Nets Project Interim Results. Seattle, WA: PATH.

insurance are included, the landed cost ranges from $3.37 to $3.92 based on the size of the net. **See Commodity Price and Leadtimes for more details.**

The Global Fund's Net Transition Initiative (NTI) runs from 2021 – 2023 and supports the transition from the UNITAID-Global Fund New Nets Project (NNP) to Global Fund internal procurement and financing of dual AI nets. 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 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.

ITN Costs

A link to cost assumptions for FY 2024 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 quality assurance. 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).[42]

ITN Ownership: Key Distribution Channels

Mass distribution campaigns

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

In line with WHO PQT standards that a net life-span of three years should be assumed, PMI will only support campaigns more or less frequently if strong local evidence exists and the country demonstrates commitment to more frequent ITN campaigns through its resource prioritization. Even though data in some places may demonstrate that ITNs are lasting less than three years, it is likely not feasible from a resource perspective alone to shorten the cadence of mass distribution campaigns. Therefore, PMI recommends that data be used to increase continuous distribution to complement mass distributions (e.g., bolstered ANC/EPI, introducing or expanding school-based or community distribution, increasing the quantities of nets going out via existing channels, 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% after the 1.8 ratio has been applied) or using data from previous mass campaigns to justify an alternative total amount.[43]

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[44]
- Mop up campaigns

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

[43] Global Fund, Malaria Information Note, July 2022.. https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf

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

- 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 partner 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 not available at the country level for campaigns, PMI works with the RBM Partnership to End Malaria Country/Regional Support Partner Committee (CRSPC) to ensure that external technical assistance can be supported. If an NMP would like to request external TA for an upcoming mass campaign, they should follow the process outlined on the CRSPC website. By exception, PMI teams may allocate MOP funds for technical assistance for campaigns, e.g., macro- and micro-planning or digitalization, if deemed a priority by the national program. Further information on mass campaigns, including a comprehensive toolkit are available through the Alliance for Malaria Prevention (AMP) website at: http://allianceformalariaprevention.com/amp-tools/amp-toolkit/.

Campaign digitalization

Digital tools are increasingly being used by national malaria programmes and their partners to support the collection, compilation, and analysis of data in a timely manner during household registration and ITN distribution activities. Digital tools can have many different uses during all campaign phases, such as macro- and micro-planning, distribution, payments, supervision, evaluation, and reporting. The use of digital tools can improve the efficiency of ITN campaigns as well as continuous distribution and enhance ITN accountability. PMI can support country efforts to sustainably incorporate the use of digital tools into ITN mass distribution campaigns. Given the investments of other partners in digitalization, coordination, communication and planning are particularly important. Consistent with the Global Fund's Technical Note, PMI encourages an integrated, multi-purpose digital platform that can be used for malaria campaigns as well as other campaigns and activities (e.g., IRS and SMC campaigns). In the long term, data collected and used for mass distribution planning, implementation and monitoring could be incorporated into the national DHIS-2 platform and could be cross referenced with continuous distribution data.

See the **Surveillance & Informatics section** and see more information here: https://allianceformalariaprevention.com/tools-guidance/improving-itn-campaign-efficiency-through-use-of-digital-tools/

https://www.crs.org/sites/default/files/tools-research/digitized_mass_campaigns_one-pager_march_4_2021-_english.pdf

Continuous distribution channels

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

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

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.[45]

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

Routine distribution of ITNs through public-sector[46] 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.

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

[46] 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 (SNP) has proven to be a feasible and effective strategy for maintaining consistently high coverage.[47] 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 sub-regions. 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 Insecticide-treated Nets 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.

[47] 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

The following indicators are currently included in all household surveys in endemic countries (MIS, DHS, and MICS):[48]

- 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[49] 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.[50, 51] The ITN access indicator measures the proportion of the population that could sleep under an ITN if every ITN available in the household were used by two people. (For more information on calculation of this indicator, see the indicator snapshot video at: https://www.youtube.com/watch?v=YfTXcc13GOI). Understood together, the population access and use indicators allow data users to distinguish non-use related to access to an ITN from that linked to behavior.

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

[48] MEASURE Evaluation, MEASURE DHS, President's Malaria Initiative, RBM Partnership to End Malaria, UNICEF, World Health Organization. Household survey indicators for malaria control. 2018. https://www.malariasurveys.org/documents/Household%20Survey%20Indicators%20for%20Malaria%20Control_FINAL.pdf

[49] 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

[50] Universal coverage with insecticide-treated nets-applying the revised indicators for ownership and use to the Nigeria 2010 malaria indicator survey data. 2013. Kilian A, et al., Malaria Jour, 12:314.

[51] 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.

countries can be found at https://breakthroughactionandresearch.org/resources/itn-use-and-access-report/.

Care of ITNs

Social and behavior change (SBC) for net use and net care is critical. Studies confirm that SBC interventions are effective at increasing use of ITNs among targeted populations. Social and Behavior Change for Insecticide-Treated Nets (2019) is an excellent resource for designing and implementing effective SBC interventions. The Malaria Behavior Survey (MBS) is a standardized tool to measure malaria-related behaviors, including ITN use and ITN care, and associated behavioral factors [52]. The MBS is a cross-sectional household survey that provides data to inform the design, implementation, and evaluation of SBC interventions and help guide evidence-based decisions about priority behaviors, including ITN use and ITN care, and the behavioral factors that influence them (See **SBC Chapter** for additional information).

ITN care should continue to be a priority component of PMI-supported SBC activities, as positive attitudes toward ITN care have been shown to have a protective effect on ITN durability.[53] Results from durability monitoring studies show that differences in median survival could be attributed at least in part to household environment and net care behaviors, so targeted SBC activities to promote ITN care and retention should be considered.[54]

PMI continues to promote guidance on ITN use and ITN care ; see: Social and Behavior Change for Insecticide-Treated Nets (2019) document. PMI previously funded an operational research study in Nigeria and Uganda to understand the knowledge, attitudes, beliefs, and practices that motivate or impede ITN care and repair behaviors and used the findings to test the effectiveness of a SBC intervention. Based on these results,[55,56] PMI will not support repair activities (e.g., distribution of ITN repair kits, SBC promoting ITN repair, etc.).

SBC activities focused on ITN care should emphasize the following ITN care behaviors:

- Tie up the net every day to keep it away from foot traffic and dirt.

[52] http://malariabehaviorsurvey.org/

[53] Impact of a behaviour change intervention on long-lasting insecticidal net care and repair behaviour and net condition in Nasarawa State, Nigeria and Impact of a behaviour change communication programme on net durability in eastern Uganda

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

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

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

- Keep children away from the net.
- Avoid storing food or crops in the same room as the net.
- Fold and store the net safely when not in use.

SBC activities should promote overall ITN care at the household level with the goal of 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 ITN care behaviors into existing ITN SBC activities or malaria SBC strategies social and behavior change communication (SBCC) strategies or other platforms.[57]

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

Environment Risks of ITN Repurposing, Misuse, and Disposal

Repurposing

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

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

In 2018, RBM issued a *Consensus Statement on Repurposing ITNs: Applications for BCC Messaging and Actions at the Country Level*[58] to provide National Malaria Programs (NMPs) 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.

Misuse

Misuse is defined as the use of a viable ITN for purposes other than its intended use as a bednet. Misuse of ITNs is not acceptable under any circumstances and not only defeats the public health purpose of providing protection from malaria, but can also have negative environmental outcomes. The most ecologically damaging use of ITNs is for fishing. Pyrethroids can kill fish, especially young fish, aquatic crustaceans, and insects when leached from a viable ITN being used for fishing. The fine mesh of treated or untreated mosquito nets may also cause ecological damage by physically removing many small aquatic animals from an area. This is less of an issue in larger bodies of water but can be a significant problem in small streams and ponds. There are no other known misuses of viable ITNs that pose serious environmental risks. Evidence in the literature indicates that misuse of ITNs can be a problem, usually in fishing communities, and multi-sectoral efforts should be made to address these situations. However, there is "very little evidence to support claims of widespread misuse across Africa.[59,60] A 2017 qualitative

[58] https://endmalaria.org/sites/default/files/Consensus%20Statement%20on%20Repurposing%20ITNs.pdf

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

[60] 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

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.[61] Other studies, such as those from lakeside communities in Lake Tanganyika and a refugee camp in the DRC reinforce the drivers identified in Malawi; ITNs are being sold to generate income to support immediate food needs.[62] [63] [64] While anecdotal reports of mosquito net fishing are growing, the magnitude of the problem remains unclear.

Should misuse be identified as an issue during the development of the initial environmental evaluation (IEE), countries may utilize the 2018 PMI Toolkit to further investigate the extent of misuse. SBC interventions can address ITN misuse by expanding traditional messages about correct and consistent net use. 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. Responding to misuse is challenging and multi-sectoral, involving Ministries of Health, Environment, and Fisheries.

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

[61] 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.

[62] 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.

[63] 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.

[64] 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

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.[65]

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

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

Durability Monitoring

Introduction

[65] In 2010, USAID sponsored a recycling pilot in Madagascar. This looked at several key factors including recovery, transporting, and parameters for converting expired ITNs into a viable alternative product. It was determined that the technology required for this process was not available in Madagascar, and that the cost to ship ITNs back to the US for processing was prohibitively high. Outside of this one recycling pilot, there is no evidence that large quantities of ITNs have ever been collected for disposal, nor has evidence been presented that there is a positive outcome in collecting ITNs for disposal. Most expired ITNs remain at the site and are either repurposed or disposed of at a household level. Please see: Nelson, Michelle, Ralph Rack, Chris Warren, Gilles Rebour, Zachary Clarke, and Avotiana Rakotomanga. 2011. *LLIN Recycling Pilot project, Report on Phase II in Madagascar.* Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3. AND Nelson, Michelle, and Ralph Rack. 2012. *Madagascar: LLIN Recycling Pilot Project, Report on Phase* III. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 7.

ITN durability monitoring was originally designed to provide programs with information needed to optimize their procurement, delivery, and effectiveness. Monitoring is intended to enable programs to identify products that perform below expectations and also provide useful feedback to manufacturers in their efforts to improve their products. To date, 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.

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

Under the current protocols, ITN durability monitoring 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 durability monitoring (upon completion of the 36-month report) are made publicly available via pmi.gov and https://www.durabilitymonitoring.org/. All PMI-funded durability monitoring activities should follow the study protocols, questionnaires, and other tools (such as budget template) available via https://www.durabilitymonitoring.org/

Given that WHO has drafted a Guideline for Prequalification Assessment of Insecticide Treated Net (ITNs), which includes a module on post-market activities, in order to align with this global effort and ensure that PMI-supported monitoring efforts are based on the current priority questions, can contribute to post-market surveillance, and are used in decision making for product selection, PMI funding should **not be used** for the initiation of new durability monitoring activities in countries where it has been conducted. Ongoing studies should be completed. Countries that have planned funding but not yet initiated activities should reevaluate whether the activity remains a high priority. PMI funding may be used to support durability monitoring in countries where it has never been implemented, where it is a high priority of the NMP, or where new types of nets are being deployed. In those countries, 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. Additional guidance on post-market monitoring activities will be forthcoming.

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

If your country team has identified specific issues with ITN quality, **please contact your PMI HQ VMCT and Supply Chain Team backstops**, who can help determine what type of monitoring may be most appropriate for the country context and concerns.

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).[66]. 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. An Initial Site Assessment (see pages 5-6 of the 2018 PMI Toolkit) should be conducted as part of the initial environmental evaluation (IEE) development process, and where no/low evidence of misuse is determined, mitigation measures should be included in the IEE. If high evidence of misuse is determined, a more extensive "Rapid Assessment" process should take place within 3 months of the IEE approval.

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

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

A. Perhaps. PMI teams may be approached to support distribution of ITNs outside of mass campaigns or routine distributions as programmed in the MOPs. Examples include distribution to IDPs/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, 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, and should be coordinated with the broader humanitarian assistance actors. See the Malaria Prevention section on **Malaria in Humanitarian Settings.** In addition, NMPs 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 NMP and PMI objectives. Please consult with the PMI VMCT and the Humanitarian Assistance POCs if a special circumstance should arise.

INDOOR RESIDUAL SPRAYING

Introduction

Indoor residual spraying (IRS) involves the spraying of insecticide on the inside walls of houses or other eligible 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 start 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 the 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 nine 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 evidence-based and done in consultation with the NMP. PMI has specified the following factors that should be considered in the choice of insecticide class: vector susceptibility /resistance status, duration of efficacy, ITNs deployment in the IRS targeted areas and cost. The choice of insecticides that can be used for IRS is limited and currently restricted to 5 classes. Each has its own advantages and disadvantages as outlined in **Table 1,** noting that residual efficacy varies depending on surface type and country.

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

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

While there are multiple insecticides within each of the recommended IRS classes, PMI will only procure specific formulated products that have a WHO PQT listing.

The five classes of insecticides for IRS in the table are neurotoxins that paralyze and subsequently kill the insect. The oldest of these, the organochlorine class to which DDT belongs, came into widespread use in the 1940s. The mode of action of the organochlorines, like that of the pyrethroid class developed in the 1970s and 80s, is on the insect neuron sodium channel, keeping it open and therefore preventing the

nerve impulse to recharge. Carbamates and organophosphates inhibit acetylcholinesterase, an enzyme in insects and humans that terminates the action of the excitatory neurotransmitter (acetylcholine) at nerve synapses. Carbamates bind loosely and reversibly to acetylcholinesterase, whereas the organophosphates bind more strongly. The most recent class to receive a recommendation by WHO PQ for IRS are neonicotinoids. These nicotine-like compounds mimic acetylcholine, tightly binding the acetylcholine receptor to cause high levels of activation and overstimulation. Neonicotinoids are slow-acting insecticides that cause mosquito mortality at 72 hours, rather than the typical 24 hours observed for other classes. This delayed mortality requires extended residual efficacy monitoring, which can be a challenge in some countries. Another potential new class (making it the sixth class) of public health pesticide, the pyrroles, is currently registered by the U.S. Environmental Protection Agency for some indoor uses (e.g., commercial kitchens). Pyrroles are not neurotoxins, but act by disrupting mitochondrial ATP production, leading to cellular death and eventual insect mortality. One member of this class, chlorfenapyr, is currently under review by WHO PQT for use in IRS.

Two WHO PQT approved IRS products, Fludora Fusion and 2Gard, are formulated with a combination of two insecticides, clothianidin + deltamethrin. Bayer, the manufacturer of Fludora Fusion, has shown 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. 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 or 2Gard in areas with deltamethrin resistance. Note it is not recommended that IRS be co-deployed in areas where PBO or dual AI nets have recently been or will be distributed.

The WHO-specified duration of effective action in Table 1 largely corresponds to results from WHO supported trials. However, PMI's operational experience has generally demonstrated effective action for the longer-lasting OP (pirimiphos-methyl CS) of at least six months on cement, mud, and wood surfaces in most countries. Operational experience to date with bendiocarb in most cases has not demonstrated effective action beyond 3-4 months, with residual activity of only 2-3 months on mud surfaces reported in five countries. However, a number of PMI focus countries in Southern Africa, West Africa and Ethiopia have shown significantly shorter residual life for several insecticides, with approximately 1-2 months residual efficacy for bendiocarb and 2-3 months for pirimiphos-methyl CS. PMI began rolling out the IRS insecticides SumiShield 50 WG in 2018 and Fludora Fusion 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 6 to 9 months.

In 2021, Tagros received a WHO PQT listing for two clothianidin-based products: Klypson (clothianidin; the Sumishield equivalent) and 2GARD (clothianidin + deltamethrin; the Fludora Fusion equivalent). PMI

VectorLink deployed these new products during 2022 IRS campaigns in Zambia and Madagascar. Results from residual efficacy monitoring of these two insecticide will be made available in subsequent end-of-spray reports (EOSR) and entomological monitoring reports on the pmi.gov website[67].

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*[68] recommends rotations, mosaics, and mixtures to slow selection of resistant vectors. As there are now multiple, similarly-priced insecticide formulations available for IRS, PMI supports subnational rotation between insecticides with susceptibility, to the greatest extent possible. As a practical option to manage buffer stocks, it may be possible to spray some districts with insecticide A, and others with insecticide B, and switch.

PMI strongly supports the phased implementation of insecticide rotations. The WHO's *Global Plan for Insecticide Resistance Management*[69] recommends that in areas where IRS is the primary form of vector control, the insecticide used should be preemptively rotated between classes annually. Cross-resistance patterns between insecticides can be complex, but as a general rule, insecticides that share a common target site should not be rotated back-to-back. An ideal rotation would deploy insecticides with different modes of action rotated annually, however for practical purposes, rotating about every 2 years should suffice. Preemptive rotations are likely the best way to prolong susceptibility and maximize the long-term cost effectiveness of insecticides. However, there are operational challenges to fully implementing the recommendations of the *Global Plan for Insecticide Resistance Management*. In particular, there are limited, albeit a growing number, of options for non-pyrethroid, long-lasting insecticides. In addition, questions remain regarding how successful rotations will be in mitigating the development of resistance, or promoting the return of susceptibility in resistant populations. Therefore, as countries conduct preemptive rotations, the effects of insecticide rotation on insecticide resistance profiles should be closely monitored and evaluated. Country teams should engage the **PMI VMCT Operational and Entomology Leads** to discuss insecticide resistance management plans, including pre-emptive rotation of insecticide, in order to appropriately consider needed monitoring and support.

[67] https://www.pmi.gov/resources/reports/

[68] http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472_eng.pdf

[69] http://www.who.int/malaria/publications/atoz/gpirm/en/

It should be noted that SumiShield 50 WG, Fludora Fusion, Klypson, and 2GARD both belong to the neonicotinoid class of insecticides, and thus switching between these products does not constitute an insecticide rotation as described above.

IRS Insecticide Procurement Policy

With the availability of multiple WHO PQ-approved clothianidin-based products for PMI procurement (i.e., Fludora Fusion, SumiShield 50 WG, Klypson, 2GARD), PMI seeks to promote competition and a balanced market. To that end, no more than 66% [within a class, assuming] of a procurement with a minimum volume threshold of 10,000 units, should go to one manufacturer, assuming at least 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 Fludora Fusion and SumiShield 50 WG is identical, thanks to the agreement negotiated at the end of the UNITAID funded NgenIRS Project, and both the Tagros products prices are comparable.;. 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 (i.e., 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*.[70]

Key issue 1: IRS in various epidemiological settings

[70] https://www.who.int/publications/i/item/9789241508940

- 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.
- To maximize available tools to countries approaching malaria elimination, PMI can support technical assistance for countries implementing reactive IRS in response to active foci as part of a malaria elimination strategy. Support for procurement of insecticides or direct implementation of reactive IRS can be supported under OR/PE, if it is a country priority and resources allow. Due to the complicated logistics and lengthy lead times, PMI policy of not supporting IRS for epidemic outbreaks remains in place. See the **Elimination Chapter** for more information.
- 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 areas or locations at increased risk identified) that can justify IRS, and if urban housing conditions allow for anticipated access with high levels of acceptance among urban community dwellers. When country teams are selecting new spray areas, for example because a decision has been made to expand or retarget the program, epidemiological data should be taken into consideration and the **PMI VMCT Operational and Entomological Leads** should be consulted.

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

IRS programs should aim for 100% coverage of all eligible structures in the area (sub-district, district, region, or other administrative unit) to be sprayed, although WHO guidelines state that coverage above 85% is sufficient to produce a community effect. After an area is selected for spraying, there are two ways to implement IRS: blanket spraying and focal spraying. Whereas blanket spraying is defined as the spraying of all houses 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 operational research in Zambia to assess the effectiveness and cost implications of focal spraying using three different targeting strategies: 1) Geographic concentration (i.e. density of structures), 2) Health facility-based (i.e highest burden areas based on HMIS), and 3) Ecological (i.e., breeding sites identified by entomological studies). Study results found that ecological targeting was associated with a 13% reduction in malaria incidence compared to geographic targeting, while health facility targeting was associated with a 35% *increase* in malaria incidence compared to geographic targeting[71]. Given these results and the further study that's needed, countries should discuss any plans for focal spraying with the **PMI VMCT Operational and Entomological Leads.**

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.

[71] Larsen DA, Martin A, Pollard D, Nielsen CF, Hamainza B, Burns M, Stevenson J, Winters A. Leveraging risk maps of malaria vector abundance to guide control efforts reduces malaria incidence in Eastern Province, Zambia. Sci Rep. 2020 Jun 25;10(1):10307. doi: 10.1038/s41598-020-66968-w. PMID: 32587283; PMCID: PMC7316765.

- When new spray areas are being considered, areas of high transmission that require only one spray round per year to cover the majority of the transmission season, should be prioritized.
- While some countries use IRS-withdrawal thresholds of "after 3 years of implementation or reduction in burden by a certain level", there is no universally accepted threshold that can be used to determine if a country can withdraw IRS. IRS withdrawal is often influenced by political or financial decisions, or the introduction of new interventions (i.e., PBO synergist and dual insecticide 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 initial 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. Furthermore, lack of detection in additional reduction in malaria indicators after several years of implementation may be indicative of the intrinsic limits of IRS to completely eliminate transmission, rather than failure of the intervention.
- 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 new types of ITNs, is a critical component of any IRS withdrawal strategy, as an increase in malaria burden when withdrawing IRS is expected. In addition, IRS should only be withdrawn if adequate access to malaria case management has been achieved in that area.
- To date, all PMI countries with IRS programs have withdrawn IRS from one area (i.e., district), with varying levels of entomological or epidemiological rebound. If IRS will be withdrawn from an area, PMI recommends discussing an IRS Exit Strategy with the NMP, 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 ACT and RDT stocks. It is prudent to expect and

plan for an increase in malaria cases following the withdrawal of IRS. Additional commodities may be needed in the former IRS targeted areas, and entomological monitoring should be continued to monitor the impact of withdrawal on the vector population..

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 2021[72], in the majority of PMI-supported countries, insecticide costs average 30% of the IRS budget, depending on the insecticide class used. The three largest cost categories were spray operations (35% of all costs), insecticide (25% of all costs), and local labor (24% percent of all costs), constituting an average of 84% of all costs. Based on results from 2021 PMI-funded spray campaigns, the average cost per person protected was $7.04 (range from $3.76 to $17.98) and the average cost per structure sprayed was $26.27 (range $12.97 to $59.80). 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. PMI supported OR looking at partial IRS (i.e. spraying insecticide on the ceiling and the top half or bottom half of the wall, rather than the entire wall) has produced encouraging preliminary results, particularly in terms of cost effectiveness. A larger study to evaluate the epidemiological impact of partial IRS is planned for 2023; if successful, this implementation model has the potential for significant cost savings for IRS programs.

Key Issue 5: Monitoring and Evaluation of IRS

- All PMI-supported vector control programs should collect entomological data for data-based decision making, and for inclusion in the PMI/headquarters entomology database. See the **Entomological Monitoring** chapter for suggested indicators.
- PMI country teams are encouraged to support routine epidemiologic monitoring, including some measure of disease burden, in areas with PMI-supported IRS activities as a means of tracking malaria trends that will help guide policy decisions (e.g., scaling down, suspending spraying, or moving from blanket to focal 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

[72] Longman, B., Won, N., Aghajanyan, A., and Sanchez, A. April 2022. PMI IRS Country Programs: 2021 Comparative Cost Analysis. Rockville, MD. PMI VectorLink Project, Abt Associates Inc.

insecticide or formulation to another are probably best answered by a review of routine entomological data from the area being sprayed.

- PMI supports the spraying of sleeping structures, and generally does not support IRS in non-sleeping spaces, such as latrines, fowl runs, grain storage, or animal shelters. If a country's national policy is to spray non-sleeping spaces in their IRS program, and the country would like PMI to support this, sufficient entomological evidence, including molecular identification of malaria vectors in these non-sleeping structures, must be documented in order to justify the added cost of extending spraying to these additional structures with PMI resources. Please engage the **PMI VMCT Operational and Entomological Leads** for further clarification.

Key issue: New types of nets and IRS

- There is little information on the use of new types of nets in areas where IRS is being conducted. In Tanzania, there was limited benefit found from the combination of Olyset Plus (PBO net) and annual Actellic IRS treatments.
- Additionally, some IRS insecticides, such as pirimiphos-methyl, are pro-insecticides, meaning they require a transformation of the product to become insecticidal. This occurs in the mosquito, usually an effect of oxidases. If PBOs inhibit oxidases, they may result in a decrease of the effectiveness of pro-insecticides. While further work is needed to understand whether this effect results in challenges for co-implementation, this should be considered when choosing interventions.
- Generally, co-deployment of new types of nets (PBO synergist and dual insecticide ITNs) and IRS should be considered for use in the same areas only if there is unequivocal evidence of increased vector and disease suppression, and sufficient vector control is in place in the rest of the malarious areas in the country. In most instances, OR/PE will be required to generate this evidence. Country teams that plan to support co-deployment of IRS and new-types of nets should engage the PMI VMCT for further guidance.

Frequently Asked Questions for IRS

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

A. As noted earlier, PMI procures insecticides that are prequalified by WHO. Typically, insecticides will arrive in-country with quality assurance documents from the manufacturer. However, to ensure due diligence, PMI requires its IRS partner to conduct independent, pre-shipment quality control evaluations. In countries where PMI conducts IRS but the insecticide was not procured by PMI, quality assurance testing must still be undertaken by PMI prior to use. Quality control testing of insecticide can be

conducted at a number of qualified laboratories; please discuss with the PMI Headquarters IRS Technical Team for more information.

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

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

Q3. 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 Contracting Officer's Representative (COR) team to monitor environmental compliance and human safety. An independent environmental assessment should be conducted every three years through the TBD Environmental Compliance central mechanism (previously 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 **PMI 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[73] manual was revised in 2020 and contains checklists for field evaluations to assist PMI managers and IRS implementing partners in monitoring compliance efforts. In addition, PMI through the PMI AIRS project developed several supervisory tools and checklists.[74]

Q4. 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, VMCT Operational Lead, Mission Environmental Officer, and Global Health Bureau Environmental Officer, who will collectively review and provide required clearances. Because countries need to allow time for completion and approval of the more time-consuming SEAs, below are illustrative lists of actions that must be included in a SEA or SEA amendment:

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

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

[73] https://d1u4sg1s9ptc4z.cloudfront.net/uploads/2021/03/2020-bmp-manual-revision-final-3-16-20-sxf-2-1.pdf
[74] http://www.africairs.net/wp-content/uploads/2012/08/AIRS-Supervisory-Toolkit.pdf

Q5. 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 NMP is supportive. Note that not all refugee and IDP camp structures may be considered eligible for IRS, as non-permeable tenting material may not absorb insecticide (see new guidance on **Malaria in Humanitarian Settings).**

MALARIA IN PREGNANCY

Key Messages

In 2022, WHO released new malaria treatment guidance supporting the use of artemether lumefantrine (AL) for the treatment of uncomplicated malaria in the first trimester of pregnancy. ACTs continue to be the recommended therapy for uncomplicated malaria in the second and third trimesters.

In 2022, WHO recommended community-delivered IPTp (c-IPTp) by trained CHWs as an additional strategy for increasing IPTp coverage among pregnant women, especially those with limited access to health services. More information including training manuals and implementation guidance on c-IPTp are available at tiptopmalaria.org. Countries interested in exploring c-IPTp within their country context may discuss the approach with the MIP technical team.

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 ANC providers, updating and printing ANC registers, and supporting timely HMIS reporting of 8 contacts (plus an additional ANC contact at 13-16 weeks to ensure timely access to the first dose of IPTp-SP).

IPTp3+ is the primary indicator recommended by the RBM SMERG. 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.

Introduction

Each year, approximately 125.2 million women living in malaria-endemic countries, including 30 million in Africa, become pregnant. For these women, malaria is a threat to both themselves and to their babies, with an estimated 10,000 maternal and up to 200,000 newborn deaths each year as a result of malaria in pregnancy. Pregnant women, particularly those in their first or second pregnancies, are particularly vulnerable to malaria as pregnancy makes her more susceptible to malaria infection and increases the risk of illness, severe anemia, and death. For the unborn child, maternal malaria increases the risk of miscarriage and stillbirth, as well as premature delivery and low birth weight (LBW)- leading causes 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, malaria-infected women usually present with symptomatic malaria, which, if unchecked, can result in severe illness for the mother as well as the potential for miscarriage or premature delivery. In these areas, WHO recommends the use of ITNs by all pregnant women and prompt diagnosis and treatment with an effective antimalarial. Intermittent preventive treatment in pregnancy (IPTp) is not recommended for pregnant women living in areas with low levels of malaria transmission, such as in Asia or selected areas of Africa (e.g., Ethiopian highlands).

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 and higher density infections in the placental blood space, 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 prematurity and low-birth weight.

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

- Intermittent preventive treatment of malaria during pregnancy
- Insecticide-treated nets, including provision prior to pregnancy or at the first ANC visit
- Effective case management of malarial illnesses and anemia

PMI supports malaria in pregnancy activities through the antenatal care service delivery platform in collaboration with NMCPs and Reproductive/Maternal Health Programs. To facilitate this collaboration and to ensure improvements in delivery and uptake of IPTp, PMI encourages countries to establish a national technical advisory body, such as MIP or ANC working groups. Coordination with other infectious disease programs (including HIV) are also important considerations for MIP services provided to pregnant women. For example, HIV infection lessens a pregnant woman's ability to control malaria infections and placental infection with malaria parasites doubles the risk of vertical transmission of HIV.[4]

Intermittent Preventive Treatment in Pregnancy (IPTp)

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 diagnostic methods. Currently, the only WHO-recommended regimen is sulfadoxine-pyrimethamine (SP), which has been shown to be safe and effective for use in pregnancy. The purpose of IPTp is to clear or substantially lower the parasites from the placenta and 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% of pregnant women in Africa attend ANC at least once during their pregnancy, and the vast majority of these women attend three or more 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.[75,76,] 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 malaria in pregnancy than providing only two doses of IPTp (absolute risk reduction for LBW was 33 per 1000 [95% CI, 10-52] for women receiving three or more versus 2 or less than two doses).[77,78,79,]

Doses can be given as often as monthly from the start of the 2nd 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.

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[75] 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.

[76] http://www.who.int/entity/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf

[77] 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.

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

[79] 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.

Due to the revised WHO policy of giving IPTp at every ANC visit starting early in the 2nd trimester, the Roll Back Malaria (RBM) Surveillance, Monitoring and Evaluation Reference Group (SMERG) and PMI recommend monitoring the percentage of women receiving three or more doses (IPTp3+). PMI countries may also monitor additional doses (e.g. IPTp4, IPTp5, and IPTp6), if desired.

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 directly observed therapy (DOT) at ANC, and may be given on an empty stomach or with food. 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 without providing any additional benefit.

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 as of the most recent review in 2022, **WHO continues to recommend its use, irrespective of SP resistance**.

Current WHO IPTp Policy Recommendations

- In areas of moderate-to-high malaria transmission, IPTp with SP is recommended for all pregnant women at **each** scheduled antenatal care visit starting as early as possible during the second trimester of gestation, provided these visits are at least one month apart. Ideally, IPTp should be administered as directly observed therapy (DOT).
- SP can be given either on an empty stomach or with food.
- Folic acid at a daily dose equal or above 5 mg should not be given together with SP as this counteracts its efficacy as an antimalarial[80].
- SP should not be administered to women receiving cotrimoxazole prophylaxis[81].

Intermittent screening and treatment in pregnancy (ISTp), which involves screening with a rapid diagnostic test (RDT) at each ANC visit and treating only women who test positive, was not found to be superior to IPTp-SP even in areas with significant SP resistance. ISTp was associated with more maternal

[80]A standard supplemental dose of folic acid for the prevention of neural tube defects is 0.4mg daily, which is safe for use with SP. Programs should encourage this low and known-standard dose.

[81]Cotrimoxazole is often used for prophylaxis of opportunistic infections in HIV-infected individuals. For pregnant women receiving cotrimoxazole, SP should not be included as IPTp.

clinical malaria episodes, and was more costly than IPTp-SP, and therefore is not being recommended by WHO for use in any settings. Some countries are continuing to implement routine screening for malaria at first ANC only, for the purposes of monitoring parasitemia trends among pregnant women (ANC surveillance). Studies suggest that data from pregnant women is similar to parasitemia in young children, and can serve as a means for monitoring trends over time and in response to interventions.

Considerations for Procuring Sulfadoxine-Pyrimethamine (SP)

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 Prequalified hard tablet 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% batch testing before release. Studies have demonstrated the necessity of batch testing SP; in a drug quality survey conducted by WHO, 33 out of 127 (26%) samples of SP (from 25 batches, produced by 18 different manufacturers) were found non-compliant in tests of the content of active ingredients, and in one study in Kenya, 45% of SP was found to be substandard. Depending on the manufacturer, SP has a reported shelf life of between 36 and 48 months.

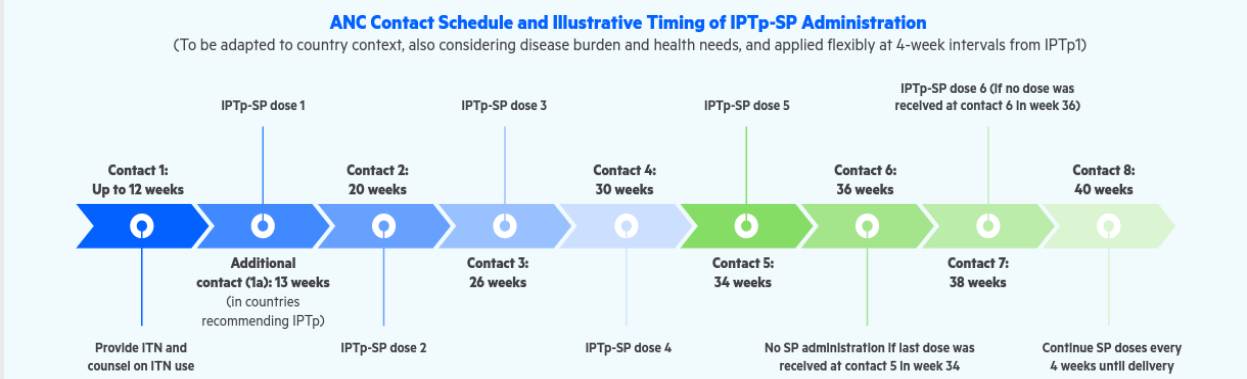
Due to consistent demand and long lead times, PMI continues to look at options to improve procurement processes for SP, including monitoring potential African manufacturers projected to become WHO Prequalified in coming years. Importation issues and registration policies continue to be key challenges 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 for SP commodity orders (please reference reference the Average Lead Time Table in **Commodity Procurement and Supply Chain Appendix 2**) 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 Sulfadoxine-Pyrimethamine and Lot Quality Control subsections within the Commodity Procurement and Supply Chain Management chapters for more information, and please reach out to the Malaria in Pregnancy team and your supply chain backstop with any questions.

As of the end of 2022, there are three WHO PQ approved dispersible SP suppliers, although PMI has yet to procure these products. Countries interested in procuring these dispersible formulations for use in IPTp should reach out to the Malaria in Pregnancy team and their supply chain backstop. For more information on dispersible SP and Perennial Malaria Chemoprevention, please refer to the Other Chemoprevention Approaches chapter.

WHO ANC Recommendations

Antenatal care (ANC) continues to be an important platform for delivering IPTp. WHO recommends a pregnant woman receives a minimum of 8 ANC contacts with a health provider during the course of her pregnancy, 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 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." 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 given at least 4 weeks prior.

Figure 1: ANC Contact Schedule and Illustrative Timing of IPTp-SP Administration



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

Opportunities for Community-Based Programming

Community MIP interventions appear to work best if CHWs are specifically trained 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 attend

ANC visits to receive their IPTp doses. Programs may wish to consider the gender of CHWs who will be working closely with pregnant women.

In addition to health promotion, CHWs may also contribute to improved IPTp coverage through community distribution of IPTp. In the June 2022 WHO Guidelines for Malaria, WHO formally recognized that community-delivered IPTp (cIPTp) by trained CHWs may offer an additional strategy for reaching pregnant women, stating: "Antenatal care (ANC) contacts remain an important platform for delivering IPTp. Where inequities in ANC service and reach exist, other delivery methods (such as the use of community health workers) may be explored, ensuring that ANC attendance is maintained and underlying inequities in ANC delivery are addressed." Consultation with NMCP, Reproductive Health, and Community Health programs are required prior to implementing delivery at community level, and materials have been developed to help guide these discussions. **Please notify the PMI MIP team about any cIPTp plans**, as there are many components to consider, including CHW workload, supply chain, and CHW gender (e.g. male/female ratio).

Information including training manuals and implementation guidance on cIPTp are available based on the TIPTOP project's best practices and lessons learned. Countries interested in exploring cIPTp may discuss this with the PMI Headquarters MIP Team. An alternate implementation approach to increase uptake of IPTp for countries to consider would be to expand their facility-based ANC outreach services to include IPTp (along with delivery and promotion of the full ANC package) as a means of reaching pregnant women in remote, rural areas.

Improving Program Implementation for IPTp

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

- Identify and assess potential issues and challenges to IPTp uptake/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 8 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, other donors and partners, such as the U.S. Peace Corps, to help facilitate MIP activities including IPTp. For example, Peace Corps Volunteers can assist facility based health workers and community health workers to increase IPTp uptake through targeted SBC strategies including mobilizing community members through household visits, organizing women's and other community group discussions, engaging men, focus group discussions, etc. Peace Corps Volunteers could also be trained to do rapid MIP/IPTp assessments in communities where IPTp uptake is particularly low to identify some of the major bottlenecks. Please see the SBC chapter for additional guidance.

Insecticide-Treated Mosquito Nets

Use of ITNs during pregnancy is a key component of PMI's malaria in pregnancy strategy. In all areas of transmission (whether moderate to high levels, or in low/elimination settings), the use of ITNs during pregnancy provides significant protection against malarial infection, illness, maternal anemia, and low birth weight. The provision of ITNs to pregnant women is part of the essential package of ANC services. ITNs should be provided to pregnant women as early as possible in pregnancy and their use should be encouraged for women throughout pregnancy and during the postpartum period. ITNs and indoor residual spraying (IRS) are the only interventions that protect women during the first trimester. Ideally, **all women of childbearing age should sleep under an ITN**, as this will ensure protection even before the woman realizes that she is pregnant. PMI supports universal coverage of ITNs to ensure women of reproductive age sleep under ITNs early in their pregnancy; PMI teams are encouraged to identify additional novel distribution channels to ensure high coverage of nets to women of reproductive age, particularly adolescent girls. **With continuing support for universal ITN coverage campaigns and maintaining high ITN ownership, countries should not lose sight of the importance of providing ITNs to pregnant women at their 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 ANC clinics resulting in a prolonged period of unavailability following the campaign. The RBM Malaria in Pregnancy and Vector Control Working Groups and the Alliance for Malaria Prevention published a joint statement detailing the importance of maintaining ITN coverage of pregnant women and infants 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. If a pregnant woman is found to have malaria, she should be treated as outlined below. There is no contra-indication to the co-administration of SP with either quinine or artemisinin-based combination therapies (ACTs), thus IPTp may be administered or not. In all instances, she should be instructed to return for IPTp in one month. If a woman is tested and found to be negative, then she should be given IPTp as usual and followed-up as per country protocol.

For uncomplicated malaria, WHO released new guidance (WHO Guidelines for malaria https://www.who.int/publications/i/item/guidelines-for-malaria) on the use of artemether lumefantrine (AL) for the treatment of malaria in the first trimester of pregnancy. This new recommendation specifically recommends AL as the ACT option for case management of malaria during the first trimester, however, WHO acknowledges that other ACTs (amodiquine-artesunate, dihydroartemisinin-piperaquine, or mefloquine-artesunate) may be used if AL is not available. This signals a departure from the prior recommendations to use oral quinine for seven days (with or without clindamycin). In the second and third trimesters, ACTs are the preferred therapy, with no preferences for which one. 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, tafenoquine, doxycycline, and tetracycline should not be used in any trimesters of pregnancy.

For treatment of severe malaria in pregnancy, parenteral antimalarials should be given without delay; severe malaria carries very high mortality rates for both the mother and fetus. Parenteral artesunate is preferred in all trimesters.

Table 2. Treatment of Malaria in Pregnancy

	1st trimester	**2nd or 3rd trimester**
Uncomplicated malaria	Artemether Lumefantrine (AL)**	ACT*
Severe malaria	IV/IM artesunate (preferred) or IV/IM quinine if artesunate not available	IV/IM artesunate (preferred) or IV/IM quinine if artesunate not available

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

** Nearly all of the data on safety of first trimester ACT use is for artemether-lumefantrine, thus WHO recommends AL as the preferred ACT treatment option in the first trimester.

Women living with HIV Infection

HIV infection increases the risk and intensity of malaria infection during pregnancy and reduces a pregnant woman's ability to control *P. falciparum* infections. HIV-infected women are 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 women living with HIV infection 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. Research studies exploring other drugs for IPTp are underway, and show benefit, but WHO has not made any recommendations on changing the drug from SP to another drug at this point in time.

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

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

Prevention of Anemia in Pregnancy

Folic acid supplementation in pregnancy is important to prevent neural tube defects in the developing fetus as well as to prevent megaloblastic anemia in the mother. The recommended dose of folic acid for use in pregnancy is 0.4 mg/day or 400 micrograms per day, which is adequate to prevent neural tube defects in the infant. In many African countries, the higher (5 mg) dosage, which is used to treat megaloblastic anemia (anemia resulting from folic acid deficiency, which is rare in pregnancy), is predominantly available. However, this higher dose should not be used in conjunction with IPTp, as it has been shown to decrease the efficacy of SP. In contrast, the 0.4 mg/day dose does not interfere with SP efficacy.

Additional Resources

- Roll Back Malaria MIP Working Group website: https://endmalaria.org/our-work-working-groups/malaria-pregnancy
- Roll Back Malaria MIP infographic, https://endmalaria.org/sites/default/files/MiP%20Infographic%2C%20updated%20EN.pdf
- 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: http://www.who.int/malaria/publications/atoz/policy_brief_iptp_sp_policy_recommendation/en/.
- The report from the Expert Review Group meeting: http://www.who.int/malaria/mpac/mpac_sep13_erg_ipt_malaria_pregnancy_report.pdf
- *The epidemiology of malaria in pregnancy* (by Desai M, ter Kuile FO, et al) and other articles in the Lancet supplement (volume 7), February 2007.
- A broad range of useful documents is also available as part of the "Malaria during Pregnancy Resource Package" produced by the Maternal and Neonatal Health Project. This can be found on their website (www.jhpiego.org) 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. Some recent studies present mixed findings on the efficacy of IPTp with SP, however WHO recommends continuing IPTp with SP until such time as there is clear evidence that it is no longer

effective or an effective alternative is recommended. There is evidence of decreasing efficacy of SP in Eastern Africa, specifically in studies from Tanzania and Malawi, suggesting that SP may be of reduced benefit in specific regions of the respective countries.[82,83,] 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.[84,85] Studies in areas with lower levels of SP resistance (West Africa) have found that IPTp with SP remains effective.[86,] In addition, a recent meta-analysis of national survey data has shown that SP provides protection in a programmatic context (e.g., non-study setting). Similarly, a meta-analysis of data from eight delivery cross-sectional studies in six countries with varying degrees of resistance found no correlation between the effect of IPTp-SP and resistance strata. Consequently, WHO recommends continuing IPTp with SP until 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 13th 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 2nd trimester, although an unskilled provider may not be able to palpate the fundus as early as 13 weeks

[82] 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.

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

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

[85] 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.

[86] 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

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 2nd trimester, it is preferred that other methods be used to determine gestational age/ whether the woman is in the 2nd trimester).

SEASONAL MALARIA CHEMOPREVENTION

New/Key Messages

Seasonal malaria chemoprevention (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 has published new guidelines supporting a more flexible approach to SMC implementation, including additional cycles, expanding age ranges, and extending to new geographies 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 sulfadoxine-pyrimethamine (SP) resistance. Results of these trials will be used to inform guidance, including monitoring for SP resistance. Initial results show effectiveness on par to that shown in the Sahel, despite high levels of genetic markers 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 seasonal malaria chemoprevention (SMC) in March, 2012.[87] Seasonal malaria chemoprevention, formerly known as intermittent preventive treatment for children, is the administration of treatment doses of longer-acting antimalarial medications at

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

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. Historically, the WHO recommendations included the distribution of a treatment dose of sulfadoxine-pyrimethamine plus amodiaquine (SPAQ) to children between 3 and 59 months of age at intervals of 28 days during the period of peak malaria transmission (typically 3-4 months) in areas of the Sahel region of Africa where minimal SP and AQ resistance has been found. However, WHO SMC guidelines were updated in June 2022 to include more flexibility in implementation of SMC, based on local epidemiology, transmission patterns or evidence of effectiveness. The new guidelines state:

> "In areas of seasonal malaria transmission, children belonging to age groups at high risk of severe malaria should be given antimalarial medicines during peak malaria transmission seasons to reduce disease burden."

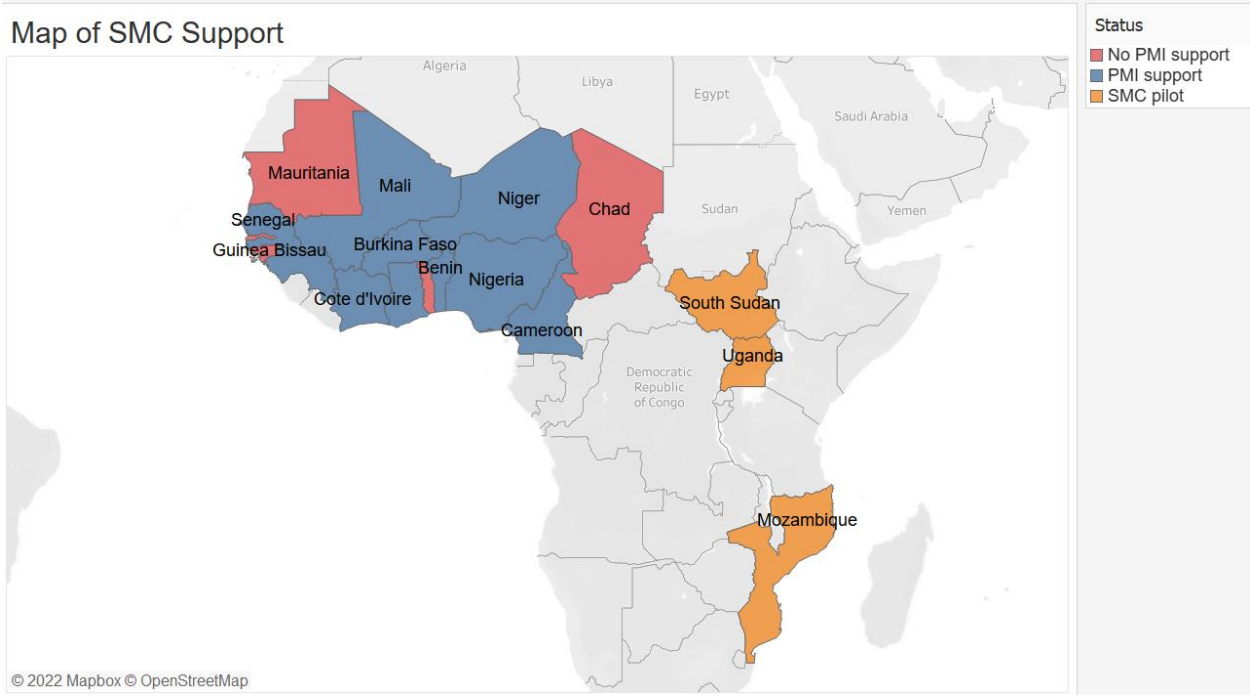
Seasonal malaria chemoprevention is only recommended for geographic regions in which 60% of malaria cases occur within a period of about four months each year. WHO recommends that countries implementing SMC should not concurrently implement Perennial Malaria Chemoprevention (formerly intermittent preventive treatment in infants or IPTi) or Mass Drug Administration in the same areas [see Other Chemoprevention Approaches for more information]).

PMI currently supports SMC activities in Benin, Burkina Faso, Cameroon, Ghana, Guinea, Mali, Niger, Nigeria and Senegal and will begin supporting Côte d'Ivoire's SMC launch this year. PMI is not currently supporting SMC with SPAQ 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, given WHO's new SMC guidelines, suggestions that SP resistance may not preclude chemoprevention efficacy with combination drugs, and preliminary feasibility and efficacy results from studies of SMC with SPAQ in Uganda and Mozambique, PMI may consider supporting SMC outside the Sahel going forward using MOP funds. However, countries not already implementing SMC that are considering using FY2024 MOP or reprogrammed funds to support SMC should consult with the technical team (see Other Chemoprevention Approaches for more information).

Seasonal malaria chemoprevention programs require a community-based structure for delivery. Many successful programs are built on existing CHW or iCCM programs, where available. Community health workers are often best placed to identify the children who qualify for SMC, distribute the medications, and follow-up to ensure adherence to dosing regimens throughout the rainy high transmission season. Results from the PMI-funded pilot implementation and evaluation of SMC in Mali and Senegal showed a 66% drop in parasite prevalence and a 50% drop in cases of uncomplicated malaria among children <5

following four rounds (months) of SMC. The studies also demonstrated the feasibility of implementing through existing community-based platforms[88]. Teams in relevant countries are encouraged to consult with the PMI Headquarters SMC points of contact to determine whether and how to support country-level SMC strategies.

Figure 2: Map of SMC 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; however, WHO is planning a revision of the SMC field manual which will hopefully be available in early 2023. 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. Countries also have piloted new delivery models such as

[88] https://malariajournal.biomedcentral.com/articles/10.1186/s12936-017-1974-x

incorporating SMC delivery into routine CHW work. 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, CHWs test febrile children prior to SMC delivery and children who test positive are treated with ACTs and do not receive SMC drugs during that cycle. 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.[89] Some countries, such as Senegal, are addressing concerns about adherence to day 2 and day 3 of SMC drug regimens by providing directly observed therapy (DOT) as part of the campaign. This comes with significant costs and is not recommended by PMI without clear evidence of low adherence for second and third doses. In most SMC campaigns, implementing partners are responsible for SBC and communication activities (See Social Behavior Change - Special Considerations). These activities can also be key to achieving coverage and adherence targets. PMI country teams are encouraged to 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 National Malaria Program (NMP) staff in other countries implementing SMC to better understand best practices and SMC-implementing countries are asked to send a PMI team representative to the annual RBM SMC Alliance meeting.

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, Uganda, and South Sudan to explore the feasibility and effectiveness of SMC in areas with seasonal malaria transmission outside of the Sahel and preliminary results are very promising (See preliminary results here and see also Other Chemoprevention Approaches).

Number of cycles

WHO recommendations specify that "the number of cycles should be informed by the duration of the high-transmission season, based on the local malaria epidemiology, and the length of preventive efficacy of the selected drug combination. SMC should be used to protect children during the entire high-transmission season." Some countries have questioned whether three cycles would be sufficient to

[89] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0193296

provide a desired level of protection, while others have considered extending the number of cycles 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 and recent implementation pilots have shown that in some settings the addition of a fifth cycle may lead to significant reductions in malaria mortality and morbidity in areas with longer transmission seasons. Additional data from countries or regions implementing additional cycles (such as coverage and adherence in cycle five, adverse drug reactions, etc.) are needed to better inform policy. Of note, evidence suggests that an additional cycle of SMC may be cost effective if an extra 10% of cases occur within that 5th month window (M. Cairns, WHO SMC Consultation meeting, 2022). 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, and in the gap analysis tables providing justification and with an email notification to the SMC team.

Age groups

The current WHO recommendation is for SMC to target children aged 3-59 months. These recommendations are based on clinical trials and pilot SMC projects which documented the effectiveness of the intervention to reduce malaria morbidity in this age group. Studies extending the age range for SMC up to age 10 years have been conducted in several countries, including a PMI-funded OR project in Mali. New WHO recommendations based on a recent evidence review (Thwing et al. unpublished review, see references) suggest that this intervention may be appropriate for children at high risk of severe malaria, which may extend to older children in some locations. However, it should be noted that SMC may become less cost effective when covering age groups at lower risk of severe disease and areas of lower malaria transmission. 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 has developed 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 and as a part of perennial malaria chemoprevention. The protocol and associated use cases will continue to be refined based on this pilot implementation. Note that direct therapeutic efficacy monitoring of SP and AQ is not supported by PMI as it would be unethical to use these drugs for treatment of clinical malaria in a standard TES protocol. Country teams interested in supporting resistance monitoring or protective efficacy assessments should consult with the Case Management team for guidance.

Commodities

One significant issue for implementing an SMC program is having the necessary quantities of quality-assured SPAQ available in advance of the malaria transmission season. By the end of 2022, there are three WHO prequalified manufacturers of the dispersible co-blister presentation of SPAQ. However, due to limited registration across all suppliers and other factors, 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. Suppliers acknowledge that registration is an important factor for PMI and are working to increase their registration profiles. 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 Headquarters Supply Chain Team to ensure sufficient quantities of SMC drugs will be available when needed. Any SMC drug needs required for potential pilots or planned expansions should also be included in commodity planning figures. In the geographies implementing SMC to an expanded age range (beyond 3-59 months), 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 PMI's procurement service agent, either GHSC-PSM or the Integrated PSA once it starts up, 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. PMI does procure additional SPAQ stock so if countries realize they require additional product at any point in time, contact your supply chain backstop and PMI will try to fulfill those needs. This buffer stock gives additional flexibility as does the recently increased supplier base. 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, DHA-piperaquine or artesunate/pyronaridine) 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 surveillance, monitoring, and evaluation. The first challenge is enumerating the target population of eligible children. While most districts (or health zones, etc.) have estimates for this figure, precision is often difficult; some children will age into and out of the eligible age 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 cycle.

Currently, the WHO surveillance monitoring and evaluation reference manual includes only one standard indicator on SMC programs:

> **Proportion of eligible children (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[90]. In general, available coverage surveys do not suggest that adherence to second and third doses, administered by caregivers, is low. The number of cycles of SMC 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 cycles (3, 4, or 5) and calculate coverage for each cycle. 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 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 RBM SMC Alliance M&E toolkit or through implementing partners (see the M&E performance framework in the link below for more details). 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 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.

[90] 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.

Digitizing SMC Campaigns

Digital tools are increasingly being used by national malaria programmes and their partners to support the collection, compilation, and analysis of data in a timely manner during SMC campaigns. Digital tools can have many different uses during all campaign phases, such as macro- and micro-planning, household enumeration, distribution, payments, supervision, evaluation, and reporting. The use of digital tools can improve the efficiency of SMC campaigns and enhance accountability. PMI can support country efforts to sustainably incorporate the use of digital tools into SMC campaigns. Given the investments of other partners in digitalization, coordination, communication and planning are particularly important. Consistent with the Global Fund's Technical Note, PMI encourages an integrated, multi-purpose digital platform that can be used for malaria campaigns as well as other campaigns and activities (e.g., IRS and ITN campaigns). In the long term, data collected and used for SMC planning, implementation and monitoring could be incorporated into the national DHIS-2 platform and could be cross referenced with other routine data for evaluation and analysis. Many materials on digitization of campaigns are available (see VC section) and SMC-specific materials are being developed (CRS 2-pager; additional guidance document available soon).

Additional Resources

- Additional information on the WHO policy recommendation can be found at: https://app.magicapp.org/#/guideline/6287
- Thwing et al. Unpublished evidence review: https://zenodo.org/record/6535577#.Y2vxgnbMI2w
- This field guide for SMC implementation, issued in 2013, from WHO could be useful for planning [note that an update of this guide is in progress]: https://apps.who.int/iris/bitstream/handle/10665/85726/9789241504737_eng.pdf?sequence=1&isAllowed=y An additional toolkit from MMV is available at: https://www.mmv.org/access/tool-kits/seasonal-malaria-chemoprevention-tool-kit
- RBM SMC Alliance SMC M&E toolkit performance framework in French and English: https://www.smc-alliance.org/sites/mmv-smc/files/content/attachments/2021-11-10/SMC%20ME%20Toolkit%20Performance%20Framework_ENGLISH.pdf
- 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
- RBM SMC alliance resources: https://www.smc-alliance.org/resources
- CRS: Two page summary of digitizing SMC campaigns: https://www.crs.org/sites/default/files/tools-research/digitized_mass_campaigns_one-pager_march_4_2021-_english.pdf

Malaria Consortium initial results from Uganda SMC study: https://www.malariaconsortium.org/resources/publications/1627/a-non-randomised-controlled-trial-to-assess-the-protective-effect-of-seasonal-malaria-chemoprevention-in-the-context-of-high-parasite-resistance-in-uganda

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 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 1,100,000 children by November 2022.

In December 2021, Gavi, the Vaccine Alliance, opened a funding window to support malaria vaccine procurement, delivery and deployment. Presently there is only one recommended product, RTS,S/AS01 and only 18 million doses will be available for the period 2023-2025. There are, however, promising results from R21 which show similar effectiveness and expected higher supply availability. A WHO recommendation on R21 is expected in calendar year 2023. WHO, through a consultative process, led the development of a Malaria Vaccine Allocation Framework to determine the allocation of the limited initial availability of the vaccine. Non-MVIP countries with moderate to high transmission malaria transmission that are Gavi eligible will begin applying to Gavi for the malaria vaccine beginning in the January 2023 application window.

It is not expected that PMI country programs will allocate FY2024 funding to directly support vaccine implementation as this will be financed by Gavi in collaboration with endemic-country financing[91], but PMI teams should consider whether complementary support might be warranted for those countries with successful Gavi malaria vaccine applications.

The PMI Malaria Vaccine Team will provide a written update immediately in advance of MOP FY 2024 development with the most up-to-date information on which countries have applied for the malaria vaccine.

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

91 Gavi. 2021. Gavi Board approves funding to support malaria vaccine roll-out in sub-Saharan Africa. Available at https://www.gavi.org/news/media-room/gavi-board-approves-funding-support-malaria-vaccine-roll-out-sub-saharan-africa

chapter will focus on one of the new complementary tools, the malaria vaccine. The introduction of the RTS,S/AS01 vaccine (hereafter referred to as RTS,S), 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 with moderate to high *P. falciparum* malaria transmission. While supply is initially highly constrained, the introduction of RTS,S is the first opportunity for deployment of a completely new prevention tool and will establish a foundation for effective delivery for future new products and increased supply.

Malaria Vaccine

RTS,S/AS01 clinical study results

Research and development towards an effective malaria vaccine has been ongoing for decades. The RTS,S malaria vaccine (developed by GSK plc with input and funding from many public and private partners) was tested as a 4-dose regimen (3 monthly doses followed approximately one year later by a 4th booster dose) in children 5-17 months of age in a Phase III trial in 11 sites across seven African countries with different transmission intensities. Despite moderate to low efficacy, the impact of the vaccine over the four years of the Phase III study showed that the number of cases averted was high: 1,774 cases of clinical malaria were averted per 1,000 children vaccinated with the fourth dose, and 1,363 cases of clinical malaria were averted per 1,000 children vaccinated with only three doses. 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 some safety signals that warranted further investigation.

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 in 2015. Subsequently, a joint meeting of the WHO's Strategic Advisory Group of Experts (SAGE) and Malaria Policy Advisory Committee (MPAC) recommended to WHO that, due a a number of unanswered questions, a large-scale pilot implementation project should be carried out with RTS,S vaccination delivered in the context of a routine immunization program in several countries in Africa. The objectives of this pilot program were to assess the feasibility of implementation of four doses of the vaccine in children 5–17 months of age, to evaluate the vaccine's impact on mortality, and to further assess the safety signals identified in Phase III trials. WHO secured funding to support this initial malaria vaccine implementation programme (MVIP) with support from the Global Fund, Gavi, and UNITAID. Ghana, Kenya, and Malawi were selected as the three pilot countries.

Pilot implementation began in Ghana and Malawi in April 2019 and in Kenya in September 2019. During pilot implementation, NMPs 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 case management interventions in the areas targeted by these pilots. The four doses of RTS,S/AS01 were integrated into national Expanded Programme of Immunization (EPI) schedules with Ghana and Kenya giving 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 training of health care workers, SBC activities, adaptation of the routing monitoring and reporting tools for use in health facilities, distribution of the vaccines and injection supplies, and supervision of deployment.

The evaluation of MVIP utilized a cluster-randomized design with approximately 60 clusters per a country, which were evenly divided between intervention and comparator districts or sub-counties. The evaluation included safety data from sentinel hospital surveillance and routine pharmacovigilance along with 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.

In April 2021, WHO confirmed that the MVIP had sufficient data to power the analysis to inform the potential recommendation for broader implementation. As of November 2022, more than 3.6 million vaccine doses had been administered, reaching over 1.19 million children with at least one dose. The MVIP will continue through 2023 during which time RTS,S deployment will extend into comparison areas.

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 (WG) met to review the existing data and make a potential recommendation related to the use of RTS,S/AS. During the meeting the WG 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 5 months of age for the reduction of malaria

disease and burden."[92] The vaccine should be administered in a 3-dose primary schedule with a minimum interval of 4 weeks between doses followed by a fourth dose provided approximately 12–18 months after the third dose to prolong the duration of protection. Based on the experience with the pilot countries, "there can be flexibility in the schedule to optimize delivery, for example, to align the fourth dose with other vaccines given in the second year of life"[93].

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

The WHO recommendation also includes an optional schedule for 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."[94] This recommendation for potential seasonal deployment is based on evidence from a study[95] in areas of Mali and Burkina Faso with seasonal malaria transmission that showed that administration of RTS,S/AS01 alone was non-inferior to seasonal malaria chemoprevention (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% reduction in clinical malaria and >70% reduction in hospitalizations and child deaths.

Initial supply availability

There is currently only one recommended malaria vaccine, RTS,S, with only one supplier, GSK plc. Following standard Gavi procedures, UNICEF has led the tender process for the overall malaria vaccine portfolio. The UNICEF tender in August 2022 secured a commitment of 18 million doses of RTS,S over the next three years. Of these, four million doses will be available in late 2023 with six and eight million doses available in 2024 and 2025, respectively. No vaccine will be available for routine implementation outside of this Gavi procurement. Pending a successful technology transfer from GSK to Bharat Biotech

[92] WHO. 2021. WHO Malaria Policy Advisory Group (MPAG) meeting- Meeting Report. Accessible at: https://www.who.int/publications/i/item/9789240038622

[93] WHO. Weekly Epidemiological Record 4 MARCH 2022, 97th YEAR No 9, 2022, 97, 61–80 http://www.who.int/wer

[94] WHO. 2021. WHO Malaria Policy Advisory Group (MPAG) meeting- Meeting Report. Accessible at: https://www.who.int/publications/i/item/9789240038622

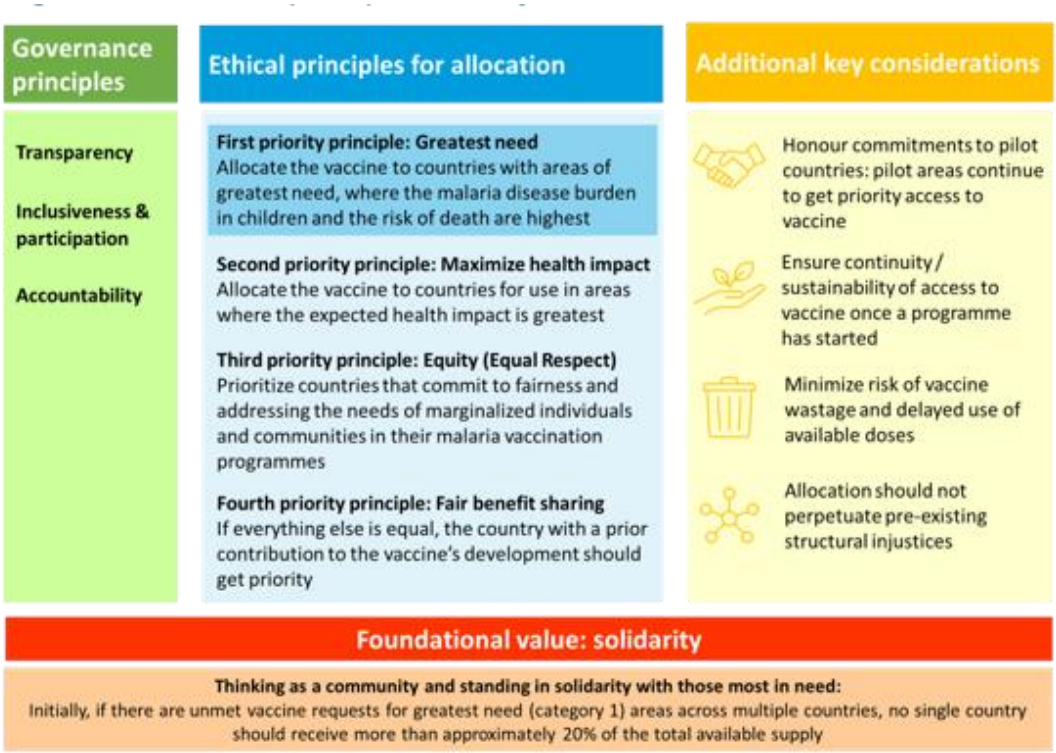
[95] Chandramohan, Daniel et al. "Seasonal Malaria Vaccination with or without Seasonal Malaria Chemoprevention." The New England journal of medicine vol. 385,11 (2021): 1005-1017. doi:10.1056/NEJMoa2026330

International Limited (BBIL), vaccine supply of RTS,S is expected to reach 15 million doses in 2026 and potentially increase up to 30 million doses a year in 2028. It is important to remember that a significant proportion of the vaccine in the next three years (7 of the 18 million) is reserved for the three MVIP countries in order to continue vaccination in the pilot areas. It is also important to note that malaria vaccine supply considerations are evolving and the PMI vaccine team will include the most up-to-date information in its update in advance of the MOP FY 2024 development.

WHO framework for allocation of limited supply

Global partners are working to accelerate increased supply through increased manufacturing capacity of RTS,S and by facilitating the development of other next-generation malaria vaccines. Nevertheless, supply is highly constrained, necessitating an ethical framework for allocation of the limited vaccine supply. WHO led a consultative process to develop the allocation framework which will guide where the initial doses of vaccine will be deployed, with an aim to prioritize supply for areas of greatest need and highest malaria burden, until supply meets demand. This framework "offers guidance on the global allocation of RTS,S/AS01, and other malaria vaccines as they become available, between countries, and guidance on prioritization of areas for vaccination within countries until supply constraints can be fully resolved."

Figure 3: Framework for principles and key considerations



Principles of the allocation framework shown above in **Figure 3** include prioritizing areas of greatest need and maximizing health impact. It also includes a commitment to fairness, recognizing that MVIP areas should continue to receive the malaria vaccine, and a solidarity cap which limits any one country from receiving more than 20% of the total available doses (currently 1 million doses per year).

The framework serves as a guide for Ministries of Health to determine the parts of the country for initial subnational vaccine introduction and it is expected to be incorporated into the Gavi application review process to inform initial allocation decisions between countries. Gavi and WHO held a series of in-person and virtual workshops from July - November 2022 to support countries to categorize their need based on under-five mortality and malaria prevalence or incidence. Initially, only those areas identified as highest need which have successful Gavi applications will receive initial supply allocations.

Current status of country applications

MVIP Countries: The three MVIP countries (Ghana, Kenya and Malawi) submitted their applications to Gavi for introduction of vaccines into the comparator areas in the pilot zones. The applications went through the review process in November 2022. All three countries expressed interest in future expansion to non-MVIP areas, which will require a complete Gavi application.

Non MVIP Countries: Twenty-four (24) countries (including 16 PMI countries) formally expressed interest to Gavi in introducing malaria vaccine. Most countries were able to attend one of the WHO and Gavi workshops. Interested countries are now working on completing the application prior to the next application deadline in January 2023. The PMI countries interested are Benin, Burkina Faso, Cameroon, Côte d'Ivoire, DRC, Ethiopia, Guinea, Liberia, Madagascar, Mozambique, Niger, Nigeria, Sierra Leone, Tanzania, Uganda, and Zambia.

Countries are required to submit a vaccine introduction application which describes how the malaria vaccine fits into a comprehensive national malaria control strategy, demonstrates how malaria vaccination will complement other malaria interventions, and describes how the malaria vaccine will be integrated within the national EPI system. Given limited supply, a high quality application is critical to securing access to the available vaccine. Countries were instructed to include the full scope of desired vaccine roll-out in line with the WHO recommendation for the malaria vaccine to be used in children living in regions with moderate to high *P. falciparum* transmission. The submitted application should contain the following:

- An updated national malaria control strategy or addendum which explains how the malaria vaccine will help the country meet its national objectives
- Detailed description of sub-national introduction of vaccine based sub-national stratification of areas according to categories of need based on the allocation framework.
- Integrated / multi-sectoral approaches where, as much as possible, the deployment of the

malaria vaccine utilizes existing health systems including the existing routine immunization systems

- Description of preparatory activities to enable vaccine introduction, e.g., training and social mobilization
- Explanation of schedule choice and delivery modalities along with strategies to minimize sub-optimal vaccine use and wastage (using the proxy of national drop-out rate between Diphtheria tetanus toxoid and pertussis (DTP3) and Measles-containing-vaccine first-dose (MCV1) and reduce drop-out rates between the 3rd and 4th dose
- Strong community engagement to ensure vaccine acceptance & resilient demand.

Gavi malaria vaccine support

In July 2022, Gavi, the Vaccine Alliance opened a process for countries to apply for the introduction of malaria vaccines into national immunization schedules in areas with moderate to high *P. falciparum* malaria transmission as defined by WHO. The support covers vaccines, i.e., vaccine dose procurement and associated supplies (e.g., injection safety devices) and financial support to facilitate the introduction (referred to as Vaccine Introduction Grant [VIG]). Countries will have access to different forms of support from Gavi. Countries will receive a VIG to support vaccine introduction costs per infant based on their Gavi co-financing status. The VIG amount ranges from $0.60 to $0.80 per infant targeted with the vaccine or $100,000 (whichever value is larger) to support the first phase of vaccine introduction. This will not cover all the costs associated with introduction; countries can access other funding sources, such as existing Gavi HSS funding. Countries seeking support to convene meetings or facilitate coordination with National Malaria Control Programs and other stakeholders are permitted to utilize existing HSS resources. Missions should keep this in mind as countries conduct their Gavi multi-year planning processes.

The first application window closed on September 13, 2022 and was limited to the three MVIP countries so that they could submit applications to prevent any gaps in vaccine deployment between the end of MVIP in December 2023 and the start of the Gavi-supported programs. A second application window, which closes in January 2023, is open to other countries with moderate to high transmission of *P. falciparum* malaria. Applications are expected to be reviewed in March 2023. Successful applications will target vaccine introduction as early as December 2023. Countries that missed the January 2023 deadline will have other opportunities (April, July, or October) later in 2023 to apply. Country applications will be submitted by national EPI programs and NMCPs are expected to work closely with their immunization program counterparts.

PMI and USG support for malaria vaccine

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.

Within countries, malaria vaccine introduction is expected to be led by national immunization programs with close coordination and complementary support from NMCPs. At this time, it is not expected that PMI country programs will allocate FY2024 funding to directly support vaccine implementation as this will be financed by Gavi[96], 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. Internal guidance has been developed for USAID and President's Malaria Initiative (PMI) staff on the strategic activities related to malaria vaccine introduction and how United States government (USG) programs can support. For example, PMI staff and implementing partners can provide technical assistance and secretariat support for Gavi malaria vaccine application development such as analyses to inform selection of high need areas and ideal timing of initial vaccine deployment, but it is expected that MoHs, Gavi, WHO, and UNICEF will play a leading role. Please contact Rose Zulliger and McKenzie Andre with any questions that you might have about ways in which PMI can support the malaria vaccine.

Malaria vaccine SBC considerations

One of the key takeaways from the three pilot countries was the importance of effective social and behavior change (SBC) strategies to promote the adoption of the vaccine while maintaining the demand for other malaria interventions. To support the introduction of the malaria vaccine, PMI may support SBC activities to promote demand for the malaria vaccine. PMI should integrate malaria vaccine SBC activities into existing PMI-supported SBC activities in areas where the malaria vaccine will be introduced. Considerations for PMI's support for malaria vaccine SBC include:

- Establish a coordination mechanism for malaria vaccine SBC that includes representatives from across the MOH, including the NMP and EPI programs.
- Development of a malaria vaccine SBC strategy integrated into both the national malaria SBC strategy and national immunization demand creation strategy.
- Simultaneously emphasizing the importance of malaria vaccine uptake as well as the uptake, maintenance, and use of proven malaria control interventions throughout malaria vaccine implementation.
- Designing and implementing data-driven SBC interventions.
- Integrating promotion of the malaria vaccine in general and in child health platforms at facility and community levels.

96 Gavi. 2021. Gavi Board approves funding to support malaria vaccine roll-out in sub-Saharan Africa. Available at https://www.gavi.org/news/media-room/gavi-board-approves-funding-support-malaria-vaccine-roll-out-sub-saharan-africa

- Supporting providers and provider-related behaviors through provider behavior change and supporting providers to advocate for the malaria vaccine and other malaria control interventions through service communication.
- Engaging with influencers on the expanded immunization schedule including the second year of life in the childhood series.
- Monitoring and responding to emerging hesitancy, rumors, and misinformation and disinformation.

The PMI SBC team and USG Malaria Vaccine Implementation Working Group are contributing to the development of global malaria vaccine SBC guidance which should be available before the introduction of the vaccine.

Malaria vaccine pipeline

This first malaria vaccine is proof that a vaccine to combat the world's oldest and longest running pandemic is possible. R21/Matrix-M (hereafter referred to as R21), from the University of Oxford, is essentially an RTS,S/AS01 look-alike vaccine. PMI sent a report to the field about the R21 candidate vaccine in April 2021. Several recent publications[97,98] documenting Phase 2 field results for the R21/Matrix-M canidate vaccine have garnered much interest but should be interpreted with caution. R21/Matrix-M is showing promising results when administered just prior to peak transmission in an area with seasonal malaria transmission. Importantly, the results achieved with R21/Matrix-M are similar to those achieved with GSK's RTS,S/AS01 in the same area.[99]

The final R21 Phase 3 data is expected in early 2023 with expectations that the manufacturer will apply for WHO prequalification shortly thereafter. The preliminary indication is that R21/Matrix-M, which is manufactured by Serum Institute of India, will be less expensive than RTS,S/AS01 and available in larger supply; however, there is no guarantee at this point. The USG will continue to monitor progress and WHO review/actions and update Mission-based staff as appropriate.

There are several other malaria vaccines in Phase 2 studies in Africa, including the PfSPZ vaccine from Sanaria. In addition, BioNTech announced[100] in July 2021 that they have a team developing mRNA-based

[97] 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 randomised controlled trial.The Lancet. 2021. 397: 1809-1818. https://doi.org/10.1016/S0140-6736(21)00943-0.

[98] Datoo MS, Natama, MH, Some A, et al. Efficacy and immunogenicity of R21/Matrix-M vaccine against clinical malaria after 2 years' follow-up in children in Burkina Faso: a phase 1/2b randomised controlled trial. *The Lancet Infectious Diseases.* 2022; https://doi.org/10.1016/ S1473-3099(22)00442-X.

[99] RTS,S Clinical Trials Partnership. Efficacy and safety of the RTS,S/AS01 malaria vaccine during 18 months after vaccination: a phase 3 randomized, controlled trial in children and young infants at 11 African sites. *PLoS Medicine.* 2014;11(7):e1001685. https://doi.org/10.1371/journal.pmed.1001685.

[100]https://investors.biontech.de/news-releases/news-release-details/biontech-provides-update-plans-develop-sustainable-solutions

malaria vaccine candidates. While in very early stages, a recent announcement on clinicaltrials.gov, states that BioNTech is aiming to begin a clinical trial of their first candidate by 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. Please contact Lorraine Soisson, Rose Zulliger, and McKenzie Andre with any questions that you might have about the malaria vaccine pipeline.

OTHER CHEMOPREVENTION INTERVENTIONS

New/Key Messages

There is renewed interest in exploring other chemoprevention interventions beyond the traditional malaria prevention tools. The use of any newer chemoprevention intervention should be carefully considered in the context of program goals and resources. All of these interventions are *complementary to* strong vector control, case management, and surveillance programs and should only be considered when these core interventions are fully implemented.

In 2022 WHO updated its guidelines for seasonal malaria chemoprevention (SMC) and perennial malaria chemoprevention (PMC- formerly referred to as IPTi) to allow for broader use of the interventions in terms of targeted age groups, targeted geographies, and treatment regimens used. There is ongoing research on the effectiveness and impact of different approaches to implementation of PMC delivered to infants and young children through the Expanded Programme on Immunization (EPI) and through community delivery systems.

WHO recently provided a conditional recommendation for IPT among school children (IPTsc); PMI does not presently support the use of IPTsc for malaria prevention outside of potential operations research.

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. WHO recently provided a conditional recommendation for MDA for burden reduction, including in emergency settings, noting low certainty evidence. It also provided a conditional recommendation based on low certainty evidence for MDA to reduce transmission of *P. falciparum* in very low to low transmission settings. WHO also provided a conditional recommendation against MDA to reduce transmission of *P. falciparum* in moderate to high transmission settings based on very low certainty evidence.

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 or less frequently deployed 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, broader age ranges for SMC) and the malaria vaccine are described in other chapters, this chapter will describe ancillary chemoprevention interventions (SMC outside the Sahel, PMC, 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 subnational stratification and tailoring (SNT), please refer to the Surveillance and Informatics section.

Any new chemoprevention intervention is intended to complement, not replace, core interventions including case management, 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. 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.

Prior to introduction of any new intervention, it is critical to consider:

Motivation and evidence

- What is the goal of introducing the new intervention and what is the gap, if any, that the new intervention might address?
- What is the evidence on impact, cost and cost-effectiveness of the new intervention and how appropriate is it for the epidemiologic / entomologic / intervention / political / social context?
- What level of basic interventions (e.g., high coverage of robust facility and community case management and vector control) should be in place before this new intervention will have added value? Will the new intervention replace any existing interventions or be combined with other interventions?

Local context and targeting

- What modifications of strategic plans or policies will be needed to include the new intervention?
- What data and models are available to inform decision-making and where do these data indicate that the new intervention would achieve the desired goal or have the highest impact?
- Which age group and geographic area will be targeted?
- What is the appropriate timing of implementation of the intervention and what barriers might exist to implementing it at that time?
- How long will we implement the intervention for?

Implementation considerations

- Who are the key national and subnational stakeholders (e.g., MCH or EPI programs)?
- What is the appropriate distribution channel for the intervention and how can its use be sustained?
- Who will lead and support training and implementation of the intervention?
- Could delivery of the new tool be integrated with any other intervention?
- What is the commodity and implementation cost? How will we pay for it? What adjustments will be required to existent investments to support this new intervention?
- Is there sufficient global commodity supply and is it possible for donors to procure the product?
- Is the national supply chain ready for this product? Has the product been approved and registered by national regulatory authorities? Is there appropriate packaging? Are there any known drug-drug interactions? What pharmacovigilance will be required?
- How acceptable is the intervention to target populations?
- What SBC and advocacy will be required? Who will lead technical inputs for the SBC design and who will pay for its implementation? How will local authorities be engaged?

Generating and using data

- How will we monitor implementation (how do we define impact & what data will be collected)?
- How will we know if we should expand / contract the scope of intervention delivery?
- What is our sustainability or exit strategy?

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 case management and surveillance practices. Ancillary interventions in low-transmission settings (e.g., mass, targeted and reactive test and treat and drug administration strategies) are discussed in the Elimination section of this guidance.

Table 3. Overview of other chemoprevention interventions

A brief description of the included interventions is in the table below.

Intervention	WHO-approved	Target population	Transmission 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 growing evidence of impact in other settings	Reduce malaria morbidity & mortality	SPAQ with ongoing studies of DP	Community (comm) campaign	Wide-scale implementation in Sahel with ongoing studies outside Sahel
PMC	Yes	Children < 2 years old	Moderate-to- high perennial transmission settings	Reduce clinical malaria, severe malaria, and anemia	SP and others	EPI	Limited use at scale with ongoing studies of new regimens
MDA	Yes, in limited settings	All ages	Elimination settings, epidemics, complex emergencies	Reduce morbidity, mortality and transmission	Many, mostly DP	Comm. campaigns; some fixed site	WHO recommended for limited settings. Limited use.
IPTsc	Yes.	School- aged children	Across transmission settings	Reduce malaria incidence / prevalence	Many	Schools	Limited ongoing data collection
Ivermectin	No rec.	All ages except infants & pregnant women	Settings with high vector control coverage and residual transmission	Reduce malaria incidence	Ivermectin	Comm. campaign	Ongoing data collection.

Seasonal Malaria Chemoprevention (SMC)

SMC is the administration of a treatment course of longer-acting antimalarial medications to children, typically amodiaquine plus sulfadoxine-pyrimethamine (SPAQ). Medications are administered at intervals of 28 days to asymptomatic children in areas of seasonal transmission where the majority of cases occur during a relatively short period. It has been shown to be an effective and feasible complementary strategy for reducing malaria morbidity in eligible countries of the Sahel by clearing existing malaria infections and preventing new infections during this high risk period (see full Seasonal Malaria Chemoprevention section). Nevertheless, use of SMC was initially restricted to the Sahel subregion of Africa due to highly-seasonal transmission and documented low levels of resistance to SP in those areas.

Recent and ongoing studies to evaluate the feasibility and protective efficacy of administering SMC in areas outside of the Sahel region have shown that SMC is an effective intervention, even in settings with high SP resistance. Recent results from a quasi-experimental prospective study of five monthly SMC cycles to deliver SPAQ to children aged 3-59 months living in seasonal transmission districts of Uganda are available here. Briefly, the study documented a 92.2% lower risk of development of confirmed malaria infection during five months of follow-up among children living in the SMC districts as compared to the control district. In 2022 WHO updated its recommendations to both allow more flexibility in age (see SMC chapter) and to remove geographic restrictions to SMC deployment. As such, the intervention is now recommended for deployment in areas of seasonal malaria transmission, regardless of drug resistance context.

While PMI country teams are not currently prioritizing SMC implementation outside the Sahel, it is possible to support SMC in new geographies with PMI resources. Any potential implementation of SMC outside the Sahel should be complementary to strong case management, malaria in pregnancy service provision, and vector control and should be accompanied by robust surveillance. Requests for PMI to support SMC outside the Sahel must be discussed with the PMI Headquarters SMC points of contact and PMI leadership, in consultation with the supply chain team. Please reach out to Catherine Dentinger, Rose Zulliger and Lia Florey if your NMCP is considering introduction of SMC or for more information.

Perennial Malaria Chemoprevention (PMC)

PMC is the provision of a full therapeutic course of a single or combination antimalarial treatment to asymptomatic children under two years of age at pre-defined intervals. It has primarily been implemented using sulfadoxine-pyrimethamine (SP) with treatment provided at 10 weeks, 14 weeks, and nine months of age, alongside routine vaccines within the Expanded Programme on Immunization (EPI). This deployment informed the development of the 2010 WHO recommendation on IPTi, which was relatively prescriptive in terms of drug, timing, and delivery. In 2022 this recommendation was revised

and WHO removed restrictions on the dosing ages and intervals and on whether the intervention could be used in settings with higher levels of *Pfdhps 540* mutations. The new recommendation provides a conditional recommendation that, "In areas of moderate to high perennial malaria transmission, children belonging to age groups at high risk of severe malaria can be given antimalarial medicines at predefined intervals to reduce disease burden" (WHO, 2022). WHO further recommends that determination of the PMC schedule should be guided by the age pattern of severe malaria admissions in each country along with feasibility, affordability, and treatment duration of protection considerations. The WHO recommendations have also noted evidence on the value of extending PMC to include children aged up to 24 months. The treatment used for PMC should be different from the first-line antimalarial.

To date, NMCPs have not prioritized PMC in any country except Sierra Leone. Sierra Leone, after piloting what was previously called IPTi in four districts in 2017, scaled up IPTi nationally to all 14 districts in mid-2018.

As shown in the table below, several funders (e.g., UNITAID, BMGF, Malaria Consortium, EDCTP) are currently supporting evidence generation to accelerate the adoption and scale-up of PMC in moderate-high transmission settings, to older age groups (i.e., through 2 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 PMCpolicies. Additionally, GiveWell has recently committed funds to support PMC in the DRC.

Donor / Project	Implementation Country	Timeline	Intervention details
UNITAID / PSI	Cameroon, Cote d'Ivoire, Benin & Mozambique	2021-2025	SP delivered by EPI at health facility (HF) and community health workers (CHWs) to children up to two years old
EDCTP / MULTIPLY	Mozambique, Sierra Leone & Togo	2021-2024	SP delivered by EPI and mobile clinics to children up to two years old
BMGF & La Caixa / ICARIA	Sierra Leone	2019- 2025	2 arms: 1) ITPi delivered by EPI; 2) IPTi delivered by EPI + azithromycin
BMGF / Malaria Consortium-IPTi Effect	Nigeria	2020-2024	3 arms: 1) SP delivered by HFs at 10 wks, 14 wks, 9 mths; 2) 10 wks, 14 wks, 7 mths, 9 mths and 11 mths 3) control

While PMI country teams are not currently prioritizing PMC implementation, it is possible to support PMC with PMI resources. Any potential implementation of PMC should be complementary to strong case management, malaria in pregnancy service provision, and vector control, and should be accompanied by robust surveillance. Requests for PMI to support PMC must be discussed with the PMI Headquarters PMC points of contact and PMI leadership, in consultation with the supply chain team.

Additionally, PMI-supported PMC implementation should be accompanied with strong monitoring and consideration of more robust analysis. Please reach out to Rose Zulliger and Laura Steinhardt if your NMCP is considering support for PMC or for more information.

Intermittent Preventive Treatment in School Children (IPTsc)

Intermittent preventive treatment (IPT) is a standard malaria prevention intervention with pregnant women and infants in selected areas, but recent data on the delivery of IPT to school-aged children (IPTsc) are limited. Studies of IPTsc have distributed treatment courses of different antimalarial drugs, including SP, SP-amodiaquine (SPAQ), SP-artesunate, artemether-lumefantrine (AL), and dihydroartemisinin-piperaquine (DP). Distribution is often implemented monthly in school-settings to school-aged children, generally aged 5-15 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. The goal of IPTsc would be to reduce malaria incidence and prevalence among school aged populations, a group that in some settings has a prevalence greater than 50% (Cohee et al., 2020). This population may also serve as a reservoir for infection. Recent evidence was shared from an evaluation of the use of DP in school-aged children in Tanzania that included 127 primary schools with over 73,00 pupils where DP was administered daily by teachers for three days every four months over a period of one year. There was good coverage and limited adverse events. The study found significant reductions in malaria and anemia prevalence at one year, but also found that the reductions in prevalence were not sustained once this intervention stopped (Makenga, 2022).

In 2022 WHO made an initial conditional recommendation for IPTsc, despite low certainty of evidence. It notes, "School-aged children living in malaria-endemic settings with moderate to high perennial or seasonal transmission can be given a full therapeutic course of antimalarial medicine at predetermined times as chemoprevention to reduce disease burden." The WHO guidelines also note that programs should only consider IPTsc "if resources allow for its introduction among school-aged children without compromising chemoprevention interventions for those carrying the highest burden of severe disease, such as children < 5 years old." Given that there are very limited geographies that have optimized coverage of existing interventions, PMI does not presently support the use of IPTsc for malaria prevention outside of potential operations research. Please reach out to Rose Zulliger and Julie Gutman if your country is currently discussing IPTsc or if you have any questions.

Mass Drug Administration (MDA)

Mass Drug Administration (MDA) of antimalarials is the provision of full therapeutic doses of antimalarial drugs to targeted populations, regardless of symptoms and without testing, at approximately the same time to all age groups of the population and often in repeated distributions. 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 originally was a broad term which encompassed some of the other chemoprevention

approaches described in this chapter (PMC and SMC), but WHO now considers these approaches to be distinct with MDA not targeting any specific ages, but rather targeting the entire population in a geography. Similarly, MDA is different from targeted drug administration (TDA) for specific populations such as forest workers. For more information about TDA, please refer to the Elimination section.

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 rounds in 4-6 week intervals.

WHO recently updated its guidelines to have distinct recommendations based on the level of transmission intensity, parasite species, whether it is a humanitarian emergency setting, and whether the goal of MDA is to reduce malaria disease burden or transmission. Further information on the updated guidelines and associated evidence and contextual information is accessible in the WHO Guidelines. 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.

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% of the population is comprised of women of reproductive age who may be pregnant, the number of women who might 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 Jimee Hwang or Rose Zulliger if your country is currently discussing MDA implementation or if you have any questions. For guidelines regarding the use of mass, targeted or reactive drug administration in low-transmission settings as a tool along with core interventions to advance elimination, see the section on Elimination.

Ivermectin

MDA with ivermectin has been a pillar of neglected tropical disease (NTD) 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 *Anopheles* 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 stand-alone 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% 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 dihydroartemisinin-piperaquine found the drug was well-tolerated and reduced mosquito survival (Smit et al., 2018). Recently, data from the MASSIV study in the Gambia on three monthly distributions of ivermectin with DP from 2018- 2019 showed a 70% lower odds of malaria infection in those living in villages that received these two drugs as compared to those living in control areas and found that the intervention was safe (Dabira et al., 2022). Ongoing studies are using different distribution strategies (stand-alone to humans and / or livestock, alongside SMC, alongside MDA) and treatment regimens.

Donor / Project	Country	Dose (µg/kg)	Combination	Timeline
MRC, DFID, Wellcome Trust / MASSIV	The Gambia	300 x 3	Ivermectin + DP MDA	2018-20
NIAID, NIH / RIMDAMAL II	Burkina Faso	300 x 3	IVM + SMC	2018-23

CDMRP / Novel vector control measure	Thailand	400 x 1	Ivermectin in humans	2016-21
MRC, DFID, Wellcome Trust / MATAMAL	Guinea-Bissau	300 x 3	Ivermectin + DP MDA	2019-22
UNITAID / BOHEMIA	Kenya, Mozambique	400 x 1	Ivermectin (humans + livestock)	2019-23

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. Please reach out to Rose Zulliger if you have any questions.

CASE MANAGEMENT

New/Key Messages

Case Management section formatting: With input from in-country staff, the Case Management (CM) chapter was reformatted starting with the FY2022 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.

PMI Priority Support for RDT/Quality Assurance and Quality Control section: There is guidance to troubleshoot problems with RDT use and report problems that persist.

Infections with parasites containing deletions in the *hrp2* gene, which produces the main antigen detected by *P. falciparum* RDTs, have been identified in Africa: In areas with known *hrp2/hrp3* gene deletions, such as in the Horn of Africa, or in geographical proximity to areas with known *hrp2/hrp3* gene deletions, systematic surveillance of *hrp2/hrp3* gene deletion should be prioritized. WHO, in collaboration with global partners, is developing a risk assessment tool to further help countries and partners prioritize these surveillance activities given competing priorities and limited funding.

WHO released a Strategy to Respond to Antimalarial Drug Resistance in Africa: The Strategy includes four main pillars focused on strengthening surveillance and containing resistance. In addition to ongoing work to support timely, high quality surveillance, PMI is collaborating with global partners to diversify the ACT market and develop strategies to deploy multiple first line treatment approaches.

WHO published an information note and hosted a series of technical consultations around the complexities of pre-referral management of severe malaria: In 2023, WHO will be releasing an implementation manual for countries that aims to offer guidance around the safe and effective deployment of pre-referral treatments.

WHO Guidelines for Malaria (updated June 2022): The updates contain guidance for the implementation of post-discharge malaria chemoprevention (PDMC), and we have included a brief section on this intervention.

Monitoring the efficacy of antimalarials section: There is updated guidance on the cost of TES and on the WHO revised guidelines for molecular correction of cases of recurrent parasitemia.

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 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[101] and other relevant clinical policies and guidelines (e.g., integrated management of childhood illness guidelines);
- Supporting the accurate quantification and forecasting, and the consistent provision of equipment and supplies to assure appropriate diagnosis (e.g., blood sampling, microscopy, rapid diagnostic tests [RDTs], biohazardous material disposal);
- Supporting the accurate quantification and forecasting, and the consistent provision of antimalarial treatment for uncomplicated (i.e., artemisinin-based combination therapy [ACT], chloroquine, primaquine) and severe (i.e., parenteral artesunate, rectal artesunate) malaria;
- Supporting quality assurance 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 the monitoring of the therapeutic efficacy of antimalarial treatments and molecular markers associated with parasite detection (e.g., *hrp2/hrp3* gene deletions) and antimalarial resistance;

[101] WHO Guidelines for malaria (2022). https://apps.who.int/iris/rest/bitstreams/1332432/retrieve

- Supporting pre- and in-service training, supervision and mentoring of clinical staff and community health workers (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 given; and
- Supporting integrated Community Case Management (iCCM) programs consistent with recommendations from UNICEF and WHO.

For additional details of PMI priority support, please see the specific *"Key Technical and Programmatic Guidance"* 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 on the presence of fever or report of history of fever[1]. 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[102].

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 case management and transmission reduction. As malaria prevention and control efforts continue to drive down malaria prevalence, continued parasitological testing of all febrile patients will remain essential, especially as the percentage of positive tests continues to decline.

The initial management of a suspected malaria patient also should include an assessment of illness severity in order to correctly classify the patient as having uncomplicated or severe disease and guide case management, including appropriate diagnostic testing, effective treatment, and referral if needed. Please see the WHO Guidelines for Malaria[1], Integrated Management of Childhood Illnesses (IMCI)

[102]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. http://www.ajtmh.org/content/journals/10.4269/ajtmh.18-0312

Chart Booklet[103], Integrated Management of Adult Illness (IMAI)[104], IMAI District Clinician Manual: Hospital Care for Adolescents and Adults, 2011[105] and Malaria Surveillance, Monitoring and Evaluation: A Reference Manual[106] for guidance.

PMI priority support for recognition and management of febrile illness

Country case management 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 both are 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. Implementation of microscopy and RDTs should be supported by a quality assurance program. Diagnosis based on clinical signs and symptoms alone should only be used when diagnostic testing is unavailable.

[103] Integrated Management of Childhood Illnesses (IMCI) Chart Booklet (2012). https://www.who.int/docs/default-source/mca-documents/imci-chart-booklet.pdf?sfvrsn=f63af425_1&download=true

[104] Integrated Management of Adolescent and Adult Illness (IMAI). https://apps.who.int/iris/bitstream/handle/10665/68535/WHO_CDS_IMAI_2004.1.pdf?sequence=1

[105] IMAI District Clinician Manual: Hospital Care for# Adolescents and Adults, 2011. https://apps.who.int/iris/handle/10665/77751

[106] WHO Malaria Surveillance, Monitoring and Evaluation: A Reference Guide. https://apps.who.int/iris/bitstream/handle/10665/272284/9789241565578-eng.pdf

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. 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.[107, 108, 109] 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 standard operating procedures (SOPs) and job aides on how to perform the test and handle and dispose of blood and biohazardous materials.

Regulations and/or laws governing who is permitted to perform a diagnostic test and dispense antimalarial drugs and antibiotics may need adjustments. For example, the task of performing RDTs in health facilities may be shifted to hospital or clinic assistants once they have been trained to conduct these tests, or the diagnosis, including the use of RDTs, and treatment of malaria may be expanded in the community by community health workers or health extension workers who have been trained on iCCM standard algorithms and malaria case management.

Training and supervision of laboratory staff

In most countries, training and supervision of laboratory personnel as part of a quality assurance program will be delivered as an integrated package. It is the responsibility of the National Malaria Program (NMP), the National Reference Laboratory, and/or the Laboratory Department of the Ministry of Health 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

[107] WHO Malaria Diagnosis website: https://www.who.int/teams/global-malaria-programme/case-management/diagnosis

[108] Universal Access to Malaria Diagnostic Testing: An operational manual (2011). https://apps.who.int/iris/bitstream/handle/10665/44657/9789241502092_eng.pdf?sequence=1&isAllowed=y

[109] Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 8 (2016-2018). https://www.who.int/publications/i/item/9789241514965

HW staff performance. Training and supervision materials, SOPs, and bench aids developed by PMI can be adapted and tailored to the country context.

Diagnostic testing: rapid diagnostic tests (RDTs)

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

RDT characteristics

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

The sensitivity of RDTs to detect parasite antigen(s) 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 most patients with clinical symptoms. While many RDTs have been shown to accurately detect both *P. falciparum* and *P. vivax* infections, the data on 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 thermal stability. 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. HRP2-based RDTs may remain positive for two weeks or more after clearance of parasitemia 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 (e.g., inverted cup, loop, pipette) 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 quality assurance, including supportive supervision, is necessary to ensure appropriate use of RDTs and adherence to RDT results. Please see the "*Behavior Change and Case Management"* subsection 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. For HRP2-based RDTs, 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-based RDT), or when there is discordance between RDT and microscopy results with ≥ 10% higher positivity rates by microscopy during routine quality control by cross-checking or when both tests are performed on the same patients.

Please see WHO's False-negative RDT results and implications of new reports of *P. falciparum* histidine-rich protein 2/3 gene deletions[110] for specific guidance.

hrp2/3 gene deletions

Although the antibodies on the RDT are designed to recognize the HRP2[111] 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 not producing the HRP2 and/or HRP3 antigens recently have been identified in Sub-Saharan Africa[112]. Although different research groups have reported detection of

[110] False-negative RDT results and implications of new reports of P. falciparum histidine-rich protein 2/3 gene deletions. https://apps.who.int/iris/bitstream/handle/10665/258972/WHO-HTM-GMP-2017.18-eng.pdf;jsessionid=B6BF2C61FB40C954A564BC0EACE1A067?sequence=1

[111] 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.

[112] Master protocol for surveillance of pfhrp2/3 deletions and biobanking to support future research. https://apps.who.int/iris/bitstream/handle/10665/331197/9789240002050-eng.pdf

generally low rates of deletions throughout the African continent, the methods used and reliability of these reports are variable. However, there is strong evidence that *hrp2/hrp3* gene deletions occur at very high levels in Eritrea, Djibouti, and Ethiopia[113,114,115,116].

Systematic surveillance of *hrp2/hrp3* gene deletion is warranted in all PMI partner countries. Countries with known *hrp2/hrp3* gene deletions, such as those in the Horn of Africa, or in geographical proximity to areas with known *hrp2/hrp3* gene deletions should prioritize these activities. WHO, in collaboration with global partners, is developing a risk assessment tool to further help countries and partners prioritize these surveillance activities given competing priorities and limited funding. WHO has developed a standardized guidance for *hrp2/hrp3* gene deletion surveillance which focuses on 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, pan-LDH or microscopy) in a random selection of health facilities.[10] Samples from any patients with a discordant result should then be assayed with molecular techniques to confirm *P. falciparum* infection and *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 a health facility survey (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. As noted above, given a limited global funding environment for *hrp2/hrp3* gene deletion surveillance, there is some need for prioritization. The Case Management team is planning to reach out to PMI country teams in prioritized countries but encourages all PMI country teams to remain aware as the situation continues to evolve. Please contact the Case Management team for more information or with questions or concerns.

Non-HRP2 based RDTs are indicated in settings with >5% 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, but there are only two non-HRP2 RDTs that are WHO prequalified so options remain limited and imperfect. Please see the Commodity Procurement

[113] 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.

[114] 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. doi: 10.1038/s41598-021-00714-8.

[115] 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. doi: 10.1038/s41564-021-00962-4.

[116] Iriart X, Menard S, Chauvin P, et al. Misdiagnosis of imported falciparum malaria from African areas due to an increased prevalence of pfhrp2/pfhrp3 gene deletion: the Djibouti case. Emerg Microbes Infect. 2020, Dec;9(1):1984-1987. doi: 10.1080/22221751.2020.1815590.

and Supply Chain Management Section for additional details, and please contact the Case Management and Supply Chain teams if you have additional questions or concerns.

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. Nevertheless, all RDTs that are WHO-prequalified meet a required minimum performance criteria and products that exceed these minimum performance criteria, such as hsRDTs, are not expected to have any significant clinical benefit over those that meet the required minimum performance criteria. Highly sensitive RDTs currently have more limited temperature stability and a significantly shorter shelf life as compared to standard RDTs. Highly sensitive RDTs may be useful for certain indications in elimination settings. Please see the Elimination section 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 pre-qualified RDTs, with exceptions only in times of severe supply shortages. PMI
does not procure specific brands of RDTs for countries ('sole-sourcing'). For guidance on procurement of single point-of-care RDTs (individually packaged with buffer) and different multi-pack options, please refer to the Supply Chain section on Types of Commodities 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[117]), only single-species *P. falciparum* tests be used. **All PMI partner 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.[15] In these countries, PMI may procure *P. falciparum*/*P. vivax* RDTs.

Despite these recommendations and guidance, some NMPs 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 NMPs 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.

[117] Universal Access to Malaria Diagnostic Testing: An operational manual (2011).

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

PMI therefore does NOT procure Pf/Pan LDH RDTs. Exceptions to this guidance will be granted if there is credible evidence demonstrating at least 5% 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 or consumption data. Correct quantification of RDTs has been a significant challenge in most PMI-supported countries, and an internal PMI analysis of MOP gap tables found wide variability in estimating RDT needs. Country teams are encouraged to take an active role during annual quantification exercises to help improve estimations. Please see the **Commodity Procurement and Supply Chain Management** chapter for additional guidance.

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. Global partners, including the WHO-Global Malaria Program and FIND, developed guidance for HWs and supervisors to troubleshoot issues with RDTs or kit accessories (e.g., blood transfer device, buffer solution) or unusual RDT results. The guidance also provides an action and reporting plan if the problems persist.[118] Facility- and community-level quality assurance should include, at a minimum, regular supervision at least every six months with observation of healthcare workers' performance of RDTs using a standardized checklist.

Laminated cards with pictures of positive, negative, and invalid RDT results also have been used to test HWs' skill at interpreting test results. Quality assurance 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.

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

[118] WHO Quality and safety practices for malaria rapid testing services

routinely comparing microscopy to RDT performance, a comparative assessment may be useful as a first step in an investigation of suspected poor quality RDTs[119].

Training and supervision of laboratory staff

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

[119] False-negative RDT results and implications of new reports of P. falciparum histidine-rich protein 2/3 gene deletions. https://apps.who.int/iris/bitstream/handle/10665/258972/WHO-HTM-GMP-2017.18-eng.pdf;jsessionid=B6BF2C61FB40C954A564BC0EACE1A067?sequence=1

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 [1,6,7]. 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 headquarters upon request. In most countries, procurement of laboratory supplies is handled by the same authorities that handle pharmaceuticals. In others, the central laboratory or individual regional or district authorities may handle procurement and/or distribution. Please refer to the **Commodity Procurement and Supply Chain Management** for more details on eligible suppliers.

Quality assurance

WHO has developed detailed guidelines on quality control of malaria microscopy[120], 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 time consuming. 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 USD $20-40 per slide), the total number of slides needed, the shipping costs (e.g. USD $500), and the need for quality assurance 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 quality assurance). 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 quality assurance by WHO Level I certified microscopists upon arrival to ensure the accuracy of the types of slides requested. Countries with access to a qualified WHO Level I certified microscopist could perform this quality assurance as part of regular activities. Countries without access to a qualified WHO Level I microscopist would require this quality assurance 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% 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 (http://dpd.cdc.gov/dpdx/Default.htm), and a CDC-developed malaria microscopy training CD-ROM or digital download (in English) can be obtained from WHO Global Malaria Programme at: https://www.who.int/teams/global-malaria-programme/case-management/diagnosis/microscopy/

Diagnostic testing: methods not recommended for clinical management

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

[120] WHO Malaria Microscopy: Quality Assurance manual. Version 2 (2016). https://www.who.int/docs/default-source/documents/publications/gmp/malaria-microscopy-quality-assurance-manual.pdf?sfvrsn=dfe54d47_2

Case Management

Treatment of uncomplicated malaria

WHO recommends six ACTs as first-line options for the treatment of falciparum malaria[121]:

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.

Antimalarial efficacy and treatment failure

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

Nevertheless, it is critically important that HWs and programs remain vigilant for potential evidence of antimalarial treatment failures. WHO defines antimalarial treatment failure as the inability to clear parasites from a patient's blood or to prevent their recrudescence after the administration of an antimalarial[122]. Incorrect dosing and poor patient compliance are more common causes for treatment failures, but poor drug quality, drug interactions and resistance to one or both active components of the ACT also must be considered. To help address incorrect dosing, poor patient compliance, and poor drug quality, please see "*PMI priority support for treatment of uncomplicated P. falciparum*" below for additional details on training and supervision of HWs and quality monitoring of drugs.

[121] WHO Guidelines for malaria (2022). https://www.who.int/publications/i/item/guidelines-for-malaria

[122] WHO. Artemisinin resistance and artemisinin-based combination therapy efficacy: status report (2018). https://apps.who.int/iris/handle/10665/274362

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 partial 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*)[123], was reported first in western Cambodia, where resistance to previous first-line antimalarial drugs also first emerged. Artemisinin partial resistance has since spread, emerged independently, or both in other areas of mainland Southeast Asia. Evidence of artemisinin partial resistance outside Southeast Asia has been limited to Guyana[124], India[125] and now Rwanda[126,127] and Uganda[128]. In response to the emergence of artemisinin partial in Africa, WHO has developed a strategy[129] to contain this resistance and strengthen surveillance. The four key pillars of the strategy are to 1) strengthen surveillance, 2) reduce drug pressure, 3) prevent spread of resistant parasites, and 4) advocate for research and development of new tools.

[123] Ariey F et al. A molecular marker of artemisinin-resistant Plasmodium falciparum malaria. 2014. Nature. 505(7481):50-5.
[124] 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.
[125] Das S et al. Evidence of Artemisinin-Resistant Plasmodium falciparum Malaria in Eastern India. NEJM. 2018. https://www.ncbi.nlm.nih.gov/pubmed/30428283
[126] 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). https://doi.org/10.1038/s41591-020-1005-2
[127] 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. doi: 10.1016/S1473-3099(21)00142-0.
[128] Balikagala B, Fukuda N, Ikeda M, et al. Evidence of Artemisinin-Resistant Malaria in Africa. N Engl J Med 2021; 385:1163-1171. DOI: 10.1056/NEJMoa2101746
[129] WHO Strategy to Respond to Antimalarial Resistance in Africa (2022). https://www.who.int/publications/i/item/9789240060265

Table 4. ACT characteristics comparison

	Artemether-lumefantrine (AL)	**Artesunate-amodiaquine (ASAQ)**	**Artesunate - SP (AS-SP)**	**Artesunate - Mefloquine (AS-MQ)**	**Dihydro-artemisinin-piperaquine (DP)**	**Artesunate-pyronaridine (AS-PY)**
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[130] 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, SSA	Ample evidence from SE Asia, SSA	Ample evidence from SE Asia, SSA	Ample evidence from SE Asia, increased risk of neuropsychiatric effects with repeated dosing	Ample evidence from SE Asia, SSA	Relatively limited evidence; acute, reversible liver enzyme increases
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 SSA	Limited evidence in SE Asia, none in SSA
Partner drug molecular resistance locus[131]	*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

[130] WHO. The use of artesunate-pyronaridine for the treatment of uncomplicated malaria (2019). https://apps.who.int/iris/rest/bitstreams/1254370/retrieve

[131] 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 Artemether-Lumefantrine and Artesunate-Amodiaquine. Am J Trop Med Hyg. 2014 Oct;91(4):833-843. https://doi.org/10.4269/ajtmh.14-0031

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. The use of AS-SP is limited to specific geographic regions (e.g., India, Middle East) due to widespread SP resistance, especially in Africa and SE Asia. MQ-AS has been used mainly in regions with multidrug resistance, such as SE Asia. DP and AS-PY have been used sparingly primarily due to higher costs, which can be 3-4 times more expensive than AL. Monitoring of antimalarial efficacy has found evidence of partial resistance to artemisinin (Rwanda, Uganda, Eritrea and Tanzania) and decreasing and sub-optimal AL efficacy (Angola, Burkina Faso, DRC, Kenya and Uganda) in sub-Saharan Africa. Along with the understanding that the next generation antimalarials are several years away, will be costly, and the most promising candidates include lumefantrine as the partner drug (e.g., ganaplacide-lumefantrine, triple ACT [TACT] using AL-AQ), PMI has been working with global partners to diversify the ACT market and decrease the overreliance on AL. In line with pillar 2 of the WHO Strategy to Respond to Antimalarial Drug Resistance in Africa, PMI recommends that all partner countries prepare and plan for the introduction of newer ACTs (AS-PY and DP) by adding them to national registrations and including newer ACTs in country treatment guidelines and in therapeutic efficacy studies as indicated. There are some situations that warrant the introduction of newer ACTs in addition to or instead of AL or AS-AQ including:

1. Seasonal Malaria Chemoprevention (SMC)
   Because SP-AQ is used for SMC, AS-AQ is not recommended as a first or second-line treatment in countries or parts of countries that conduct SMC.

2. Waning or poor ACT efficacy
   Despite overall high efficacy of AL and AS-AQ in Africa, there are some instances where treatment efficacy is poor or appears to be waning. Efficacy should be monitored regularly for a significantly declining trend of treatment efficacy over time, even if not below the WHO-specified 10% failure rate for a change of ACT. NMPs, 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.

3. Artemisinin partial resistance
   As noted above, Rwanda, Uganda, Eritrea and now Tanzania (unpublished) have found evidence of emerging artemisinin partial resistance. Although current ACTs remain clinically efficacious,

the reduced efficacy of artemisinin places more selective pressure on the partner drug. To help maintain clinical efficacy and reduce selective pressure on the partner drugs, WHO recommends that alternate strategies be considered, including the introduction of newer ACTs and longer treatment courses with currently used ACTs. Additionally, single dose primaquine should be included in the treatment regimen as a transmission reducing drug (please see below "Single low dose primaquine for *P. falciparum*").

4. Pre-emptive switch to an ACT or ACTs with different partner drugs
   Because lumefantrine is a key partner drug with next generation antimalarials, even countries without current evidence of declining AL efficacy should still consider the introduction of newer ACTs to reduce drug pressure on lumefantrine. Global efforts are underway to reduce the cost of newer ACTs.

Multiple first line therapies

Deploying multiple first-line therapies (MFTs) has been suggested as a strategy to reduce drug pressure and therefore delay the emergence and spread of antimalarial resistance where it has not yet developed. Implementation of MFT can take multiple forms, including: geographic segmentation, where different administrative units receive different ACTs; cycling strategies, where the entire country changes ACT at a fixed interval; age segmentation, where for example pediatric formulations are from a different ACT than adult formulations; or health systems segmentation, where for example CHWs use a different ACT than health facilities.

By definition, assessment of MFT effectiveness in delaying the emergence and spread of drug resistance would necessitate its full implementation at scale and realistically could not be done in a randomized fashion. As such, the evidence base for its effectiveness comes from modeling studies, which suggest it should be effective in reducing the emergence and spread of drug resistance, although with different effectiveness depending on the implementation strategy [132,133,134]. Countries are urged to reach out to the case management team to consult on planned MFT strategies.

[132] Boni MF, Smith DL, Laxminarayan R. Benefits of using multiple first-line therapies against malaria. Proc Natl Acad Sci USA 2008;105: 14216–21. doi: 10.1073/pnas.0804628105

[133] Smith DL, Klein EY, McKenzie FE, Laxminarayan R. Prospective strategies to delay the evolution of anti-malarial drug resistance: weighing the uncertainty. Malar J. 2010; 9:217. doi: https://doi.org/10.1186/1475-2875-9-217

[134] Nguyen TD, Olliaro P, Dondorp AM, Baird JK, Lam HM, Farrar J, et al. Optimum population-level use of artemisinin combination therapies: a modelling study. Lancet Glob Health. 2015 Dec;3(12):e758-66. DOI: 10.1016/S2214-109X(15)00162-X

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 malaria (2022)/Management of malaria cases in special situations/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 R&D status, none should be considered during FY 2024 MOP planning. For the latest information on products in development, please refer to the Medicine for Malaria Venture (MMV) website (MMV's pipeline of antimalarial drugs | Medicines for Malaria Venture).

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).

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. As noted above, PMI recommends that national policy and guidelines be reviewed and updated as necessary to include newer ACTs. Guidelines should be informed by the results of the latest therapeutic efficacy study (TES) and other relevant investigations (e.g., acceptability studies). In countries with a substantial private sector, the types and amounts of antimalarials being prescribed should be considered when selecting an antimalarial(s) for the public sector (please see the "Service Delivery in the Private Sector" section below for additional information).

PMI Headquarters has developed a checklist that can guide the process of reviewing national treatment guidelines, available upon request.

Equipment and supplies

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

PMI is currently reviewing the guidance on implementing MFTs as a strategy to mitigate the development of antimalarial resistance. Prior modeling studies had mixed results and the implementation of MFTs likely would result in higher costs and increased challenges with the supply chain, HW training, and social behavior change targeting beneficiaries. Pilots with support from other donors and PMI are currently underway to further evaluate the feasibility, acceptability and effectiveness of various MFT strategies. An MFT approach may be a necessary adjustment to allow for the introduction of the more expensive newer ACTs.

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

Quality monitoring of antimalarial 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 quality assurance 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 healthcare worker staff

Training curricula for clinicians and CHWs should be periodically revised to align with the country's most updated malaria case management policies and guidelines, including integrated management of childhood illness guidelines and other integrated guidelines for surveillance of febrile illness. Whenever feasible, clinical training on malaria case management should be incorporated into training on the management of childhood illness. In addition, experience suggests that coordinated training of clinical and laboratory staff, in those facilities with laboratories, improves clinicians' understanding and interpretation of the diagnostic testing results. After training, periodic supportive supervision of clinicians and CHWs will be required. When possible, such supervision should be built into existing functional supervisory mechanisms, guided by structured checklists, and focus on real-time problem-solving. Generic training and supervision materials and checklists for facility-based clinicians are available upon request from PMI headquarters staff. 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.[135]

Parasitemia should be monitored at least every 12 hours during the first 2–3 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 3 day course of an ACT.

Toolkits and other helpful information about severe malaria are available at https://www.severemalaria.org/ , WHO Guidelines for malaria (2022). and WHO Management of Severe Malaria: A Practical Handbook (3rd Edition).

Peripheral health facility and community level management: pre-referral rectal artesunate and appropriate referrals

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 followed by a full treatment course of ACT and, if possible, microscopy to quantify and follow parasite burden.

WHO recommends rectal artesunate only for the pre-referral management of severe malaria in children aged 6 years or less. Children aged 6 years 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. In 2022, the WHO published an information note[136] and hosted a series of technical consultations around the complexities of pre-referral management of severe malaria. In 2023, WHO will be releasing an implementation manual for countries that aims to offer guidance around the safe and effective deployment of pre-referral treatments like rectal artesunate.

Challenges to widespread implementation of appropriate severe malaria case management include underdeveloped or non-existent community-based platforms for delivery and referral systems,

[135] Arjen M Dondorp et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. Lancet. 2010 Nov 13;376(9753):1647-57. DOI: 10.1016/S0140-6736(10)61924-1.
[136] WHO. The use of rectal artesunate as a pre-referral treatment for severe P. falciparum malaria (2022). https://www.who.int/publications/i/item/9789240042513

inadequate availability of severe malaria and other 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. Unfortunately, referral completion for children with suspected severe malaria varies by country and can sometimes be low.[137] Similar to initial care-seeking barriers, obstacles to referral can be rooted in individual, cultural, financial, geographic, and health systems factors. These can include: improvement in a child's health, time constraints, day of the week, the caregiver needing to care for other children, perceptions on medication stock-outs at the referral facility, distance to referral facility, and costs associated with transportation and referral health care.[138, 139, 140, 141] Identifying local barriers to referral is an important step in improving the continuum of care for severe malaria. Subsequently, the importance of completing timely referral following a severe malaria diagnosis should be strongly emphasized during training of health care workers and in communication with patients. In addition, the message that pre-referral treatment alone is not a substitute for management of severe malaria at a referral center should be included in the counseling by HWs and SBC materials. Please see the "Severe Malaria Treatment and Referral" section of the Community Health technical guidance for additional information on the continuum of care for severe malaria referral and potential community-level solutions.

[137] Brunner, NC. et al. Prereferral rectal artesunate and referral completion among children with suspected severe malaria in the Democratic Republic of the Congo, Nigeria and Uganda. BMJ Global Health 2022;7:e008346. doi:10.1136/bmjgh-2021-008346

[138] Jarolimova, J. et al. Completion of community health worker initiated patient referrals in integrated community case management in rural Uganda. Malaria Journal (2018). 17:379. https://doi.org/10.1186/s12936-018-2525-9

[139] Lal et al. Caregivers' compliance with referral advice: evidence from two studies introducing mRDTs into community case management of malaria in Uganda. BMC Health Services Research (2018) 18:317. https://doi.org/10.1186/s12913-018-3124-8

[140] Give et al. Strengthening referral systems in community health programs: a qualitative study in two rural districts of Maputo Province, Mozambique. BMC Health Services Research (2019) 19:263. https://doi.org/10.1186/s12913-019-4076-3

[141] Brunner, NC. et al. Prereferral rectal artesunate and referral completion among children with suspected severe malaria in the Democratic Republic of the Congo, Nigeria and Uganda. BMJ Global Health 2022;7:e008346. doi:10.1136/bmjgh-2021-008346

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 rectal artesunate, a country must update their case management guidelines to be consistent with WHO guidelines (e.g., indicated only for those younger than six years), update their training material to reflect WHO guidelines, or (preferably) both.

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

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

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

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

Malaria case management 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 <5kg 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 (2022) for guidance regarding HIV and other special populations.

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

Among infections caused by non-*P. falciparum* species (*P. vivax*, *P. malariae*, *P. ovale*, and *P. knowlesi*), *P. vivax* is the most important, resulting in approximately 10% of malaria cases globally. Although prevalent in endemic areas of Asia, Central and South America, the Middle East and Oceania, *P. vivax* is uncommon in most of sub-Saharan Africa, except for the Horn of Africa, Mauritania, Mali, and the island of Madagascar[142].

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)[143], 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).[144]

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 US 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 addition, a quantitative point-of-care test, Standard G6PD Test manufactured by SD Biosensor, is currently

[142] WHO Guidelines for malaria (2022). https://www.who.int/publications/i/item/guidelines-for-malaria

[143] WHO. A framework for malaria elimination (2017). http://apps.who.int/iris/bitstream/handle/10665/254761/9789241511988-eng.pdf

[144] WHO "Testing for G6PD deficiency for safe use of primaquine in radical cure of *P. vivax* and *P. ovale* malaria. https://apps.who.int/iris/bitstream/handle/10665/250297/WHO-HTM-GMP-2016.9-eng.pdf

approved by Global Fund's Expert Review Panel Process for Diagnostic Products and Australia's Therapeutic Goods Administration (TGA). PMI can procure this test using the central supply chain mechanism. Please refer to the commodity costing table for the cost of the biosensor unit and the test strips.

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% to 62% among clinical cases, leading to a predicted 38% reduction in transmission, equivalent to over 214,000 cases averted cumulatively over 5 years of implementation.[145] 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. Brazil recently completed a Tafenoquine Roll out STudy (TRuST) to assess the feasibility of providing G6PD testing and appropriate radical cure (either primaquine or tafenoquine) in a real-world setting. Preliminary results presented at ASTMH 2022 showed promising results. Tafenoquine for children 2 years and older has been approved by the Australian TGA in March 2022 and marketing authorization applications are planned for several *P. vivax* endemic countries.

In countries with co-endemic vivax malaria, diagnosis needs to incorporate *P. vivax* detection (see *"PMI priority support for RDTs"* above) and treatment strategies that incorporate both the blood stage treatment and radical cure and for preventing relapses in pregnant women.[146] 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. In November 2022, WHO updated its primaquine dosing guidelines to recommend an additional treatment option of using primaquine 0.5 mg/kg/day for seven days but against using the higher 1.0 mg/kg/day for seven days.

Post-discharge Malaria Chemoprevention (PDMC)

In June 2022, the update to the WHO Guidelines for Malaria[1] included information on an intervention called post-discharge malaria chemoprevention (PDMC), which is the administration of a full antimalarial

[145] Nekkab N, Lana R, Lacerda M. Estimated impact of tafenoquine for Plasmodium vivax control and elimination in Brazil: A modelling study. PLoS Med. 2021 Apr 23;18(4):e1003535. https://doi.org/10.1371/journal.pmed.1003535

[146] WHO Guidelines for malaria (2022). https://www.who.int/publications/i/item/guidelines-for-malaria

treatment course at regular intervals to children admitted with severe anemia in settings with moderate to high malaria transmission. The purpose of PDMC is to prevent new malaria infections in children admitted with severe anemia during the period after hospital discharge when they are at high risk of readmission or death. The guidelines specify the contraindication that individuals should not receive both PDMC and other forms of malaria chemoprevention (e.g., seasonal malaria chemoprevention, mass drug administration). If your PMI program is considering the inclusion of PDMC into its programming, please reach out to the Case Management team. Please see the Other Chemoprevention Approaches section for more information about other targeted chemoprevention interventions.

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 partner countries, opportunities to partner with private sector providers and other non-public entities on key service delivery activities have been identified to further promote access and 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 countries, non-profit and faith-based facilities already receive support and oversight from the Ministry of Health, essentially functioning like an extension of the public health system. Other private providers may or may not be overseen by pharmaceuticals/drug regulatory boards or other regulatory authorities, depending on the country.

The private sector can provide a significant proportion of malaria services (ranging from less than 10% to over 50% 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., case management, malaria in pregnancy) in the private sector is critical for expanding malaria case management 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 behavior change and communications activities for providers and patients, and collection and reporting of diagnostic and treatment data. It should be recognized that appropriate messaging for private sector case management 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[147] is available for more information.

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

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

Equipment and supplies

Commodities (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 Case Management team.

Case Management Surveillance, and Monitoring and Evaluation

Case recording and reporting

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

Quality of Case Management Services

Monitoring the quality of HW performance and of key diagnostic and treatment services is an important component of a comprehensive case management program. PMI encourages the analysis and use of data collected during supervision (e.g., assessment for fever and illness severity, ordering a diagnostic test based on symptoms, correct performance of RDT steps, appropriate treatment based on test result) to monitor trends and identify gaps in the quality of care which are used to develop corrective action plans.

Other sources of data may include periodic health facility surveys (HFS) that include indicators on the quality of malaria case management, such as the Service Provision Assessment, a malaria specific HFS, 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 Informatics chapter for details on the various health facility surveys.

Monitoring the efficacy of antimalarial drugs

Routine, periodic monitoring of the efficacy of antimalarial drugs using therapeutic efficacy studies (TESs) is recommended for all PMI partner countries. 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[148]. To help sustain the capacity of national testing teams, NMPs may conduct such

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

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.

In 2021, WHO revised guidelines for molecular correction[149] [150] of cases of recurrent parasitemia in TES for the first time since 2007. Key updates included the replacement of the *glurp* marker with a microsatellite marker, and the recommendation to replace gel electrophoresis with capillary electrophoresis. The revised guidelines also include updated methods for statistical analysis of the genotyping data.

[149] Hastings IM, Felger I. WHO antimalarial trial guidelines: good science, bad news? Trends Parasitol. 2022 Nov;38(11):933-941. doi: 10.1016/j.pt.2022.08.005. Epub 2022 Sep 3. PMID: 36068129. https://pubmed.ncbi.nlm.nih.gov/36068129/

[150] WHO. Informal consultation on methodology to distinguish reinfection from recrudescence in high malaria transmission areas (2021). https://www.who.int/publications/i/item/9789240038363

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 NMPs, PMI provides support through technical and support staff based in-country, technical experts and PMI support staff based at headquarters, and implementing partner staff. This allows for regular technical interactions with local investigators conducting TESs and helps to ensure the quality and timely sharing of the final product.

PMI and the Global Fund have supported the majority of the TESs in PMI partner 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 partner 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 partner countries in Africa.

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 seven blood lumefantrine levels) or molecular testing being done in country; please see Table 4 for details. PMI suggests budgeting $100,000-175,000 per site (the lower end for one antimalarial, the higher end for two antimalarials for standard sample size with 100 participants per antimalarial per site), which includes costs for implementation and supplies. This estimate does not include the funds needed for laboratory testing for molecular correction, molecular markers of resistance, or *hrp2/3* gene deletion monitoring. For information on estimating these costs, see the Table below.

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 quality assurance 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, for ACTs not currently being used in the country, may be requested as a donation from the manufacturer coordinated through a collaboration between PMI and Medicines for Malaria Venture; please contact the Case Management Team for assistance. WHO-prequalified medicines available through the Central Medical Stores may also be used, as long as information on the manufacturer, batch number, and expiry date are available and the medicines are stored under acceptable conditions (generally <30°C).

Partnership for Antimalarial Resistance Monitoring in Africa

The Partnership for Antimalarial Resistance Monitoring in Africa (PARMA) network was established to support the monitoring of resistance-conferring *k13* mutations and other mutations associated with partner drugs in PMI countries in sub-Saharan Africa. Activities of the network 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. The 2022-2027 PARMA strategy was designed to expand the proportion of analyses done in African laboratories over the next 5 years.

PMI is implementing measures to shorten the time between completion of a TES and release of actionable resistance and efficacy information within a 6 month period. Thus, data results will be shared and programmatic implications discussed with NMPs as soon as possible and will not await the corresponding manuscript for publication. Rapid public sharing with groups such as the WHO, the Worldwide Antimalarial Resistance Network also is strongly encouraged to enable potential decision-making in a timely manner. The PMI Headquarters PARMA Team will work with teams to ensure that protocols and transfer of samples conform to all U.S. and international ethical standards.

Expenses related to capacity-strengthening visits to CDC/Atlanta or a PARMA hub in Africa (a laboratory worker from the TES country learning the techniques and testing samples during a 8-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 NMP or a well-established malaria laboratory. Once a country has participated in PARMA, there are several options for carrying out the resistance monitoring work in subsequent studies, depending on the laboratory capacity and human resources in the country. These options have different budgetary considerations which can be discussed with the TES/PARMA team at PMI headquarters (see Table 2).

Table 5. Items that may be added to a standard TES with budget implications

Please discuss with Leah Moriarty, Irene Cavros or Mateusz Plucinski to discuss specific needs for your country.

Item	Purpose	Cost implications	Partner Responsible

Lumefantrine level blood testing	If evidence of low/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) 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 implementing partner
DNA extraction kits	To extract DNA from dried blood spot samples before PARMA training	Varies based on sample size	TES implementing partner
Microscopy QC	To perform quality control on microscopy for a sample of TES slides	Varies based on partner and sample size	TES implementing partner (may subcontract with external lab)
PARMA training (ATL)	To strengthen country capacity to monitor antimalarial resistance	$12,000 per trainee	TES implementing partner
PARMA training (Africa)	To strengthen country capacity to monitor antimalarial resistance	$12,000 per trainee for travel **plus** cost of	TES implementing partner

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

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

Social and behavior change activities should be tailored to focus on either client behavior or provider behavior, and then further specified towards client groups (e.g., caretakers, pregnant women) and provider cadres (e.g., community health workers, clinicians). Although these objectives and approaches

are different, activities to address them can be done concurrently. The Blueprint for SBC in Service Delivery details approaches to addressing specific behaviors for these groups.

Health Systems Strengthening and Case Management

Case management activities contribute to strengthening all recognized core HSS functions including medical products, vaccines, and technologies (e.g., strengthening forecasting, quantification and supply chain systems, consistent provision of supplies); human resources for health (e.g., pre and in-service training); service delivery (e.g., supervision and mentoring), health finance; health governance (e.g., technical support to NMPs); health information (e.g., support for data collection, reporting, analysis and use). Please see the HSS section 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 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.
- As of 2021, PMI funds from any fiscal year may be used to pay CHWs for their work in delivering community-based malaria case management services. This guidance and a more detailed FAQ document are designed to promrefpt thoughtful and realistic planning for countries choosing to use their MOP funds in this way.
- 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.
- Many questions remain on how to tackle the complex systems challenges that affect community-based service delivery. PMI is currently funding OR on innovations to address challenges in CHW supervision and community-level supply chain, along with core investments in understanding CHW/health system touch points from a behavioral lens, in improving guidance for community-level data, and in tools for institutionalizing integrated community case management (iCCM).
- Given the concerning findings of the CARAMAL study, this year's guidance contains an expanded section on referral systems, since rectal artesunate alone without appropriate follow up does not lead to a good prognosis.
- This year's guidance also contains new sections on monitoring community health systems and on keeping community-based malaria services resilient.

Investing in Community Health

PMI's strategy recognizes that transforming and extending community and frontline health systems is essential to our goal of ending malaria faster. Malaria-specific interventions are only as strong as the systems that underlie them. Health systems strengthening, especially at the community level, is complex, with many actors involved, and many challenges to overcome. PMI teams are encouraged to engage, alongside NMPs, with other community health stakeholders to coordinate our investments aligned with national priorities for delivering community health services and strengthening community health systems. It is important to recognize the many demands on community health workers and community health systems, and strong PMI engagement is important for ensuring that community-based malaria services remain a prominent part of the conversation.

For community-based malaria services delivered through integrated platforms, such as integrated community case management (iCCM), PMI funds may be used to support the full, integrated platform (see details in iCCM section), with the exception of supplies or treatments for non-malaria diseases. PMI funds may also be used to invest in components of community health systems, where a link can be made between the system investment and delivering on outcomes within PMI's mandate of reducing malaria-related morbidity and mortality. These system components may include an enabling policy environment; community health worker (CHW) selection, saturation, scope, skills, supervision, supplies, and salaries; and data systems. Some of PMI's investment will likely include PMI country team or implementing partner level of effort (LOE) to formally engage in ongoing processes to strengthen community health systems. Financial investment in community health systems is strongly encouraged to be done with co-investment with government, bilaterals, and other donors, and with other streams of USAID health funding, and in alignment with national priorities for community health.

For PMI partner countries that are a part of the Community Health Roadmap (Burkina Faso, DRC, Côte d'Ivoire, Ethiopia, Kenya, Liberia, Malawi, Mali, Mozambique, Niger, Uganda, Zambia), national community health investment priorities are summarized on the Community Health Roadmap website.

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, volunteers, and informal community health providers, the organizational intermediaries for which they might work, health and political structures, and other government structures.[151] Community health

[151] 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

workers (CHWs) are often at the 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 health workers 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.[152] Countries may also have multiple cadres of health workers 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 all encompassing term to describe lay health workers who are based in the community and have been trained to provide health services, including, but not limited to, integrated community case management (iCCM) of children under five or community case management of malaria (mCCM) for older age groups. CHWs also play a key role in health promotion/ 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 World Health Organization 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 to deliver safe and high-quality services.[153] 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. The 2018 WHO guidelines on optimizing CHW programs and other global studies have documented: the stronger the systems

[152] Perry, H. (2021). Health for the People: National Community Health Worker Programs from Afghanistan to Zimbabwe. Accessible at: https://chwcentral.org/wp-content/uploads/2021/11/Health_for_the_People_Natl_Case%20Studies_Oct2021.pdf
[153] World Health Assembly. Community health workers delivering primary health care: opportunities and challenges. 2019. Accessible at: https://apps.who.int/gb/ebwha/pdf_files/EB144/B144_R4-en.pdf

supporting community health worker programs, the better their performance, and the greater their impact on malaria and other diseases[154],[155].

Since stronger community health worker programs help reduce malaria-specific mortality, morbidity and accelerate malaria elimination[156],[157] PMI and the National Malaria Programs we support share a strategic interest in strengthening their performance to improve access to quality malaria services[158]. Therefore, this section of the technical guidance covers both the *services* delivered by CHWs (iCCM, malaria community case management [mCCM] for all ages, proactive community case management [ProCCM], community distribution of intermittent preventive treatment in pregnancy (IPTp), social behavior change (SBC), referral for severe malaria, quality of care for these interventions) as well as the essential *systems* that support the delivery of these malaria services. These systems are often broader than malaria and include the overall functioning of local health services and 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[159] and the Exemplars in Global Health platform on Community Health Workers which uses evidenced-based country case studies to identify common pathways/lessons learned of some of the most successful CHW programs in order to help guide public health decision makers working to improve the performance of national CHW programs. Please also contact the Community Health team leads (Annē Linn and Eric Tongren) to request additional information or resources that might be relevant for your country.

Community Health Services

Community health workers are implicated in a great many community-based services, some of which are described at lengths in other sections of this technical guidance. The following table describes the

[154] Panjabi, R. et al (2020) Exemplar Community Health Worker Programs. Exemplars in Global Health. Available at: https://www.exemplars.health/topics/community-health-workers

[155] WHO guideline on health policy and system support to optimize community health worker programmes. Geneva: World Health Organization; 2018. Available at: http://apps.who.int/iris/bitstream/handle/10665/275474/9789241550369-eng.pdf

[156] Landier, J., et al. (2018). Effect of generalised access to early diagnosis and treatment and targeted mass drug administration on *Plasmodium falciparum* malaria in Eastern Myanmar: an observational study of a regional elimination programme. *The Lancet.* 391(10133). https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30792-X/fulltext

[157] Landier, J. et al. (2016). The role of early detection and treatment in malaria elimination. Malaria Journal 15(363). https://malariajournal.biomedcentral.com/articles/10.1186/s12936-016-1399-y

[158] Rozelle JW, Korvah J, Wiah O, et al. Improvements in malaria testing and treatment after a national community health worker program in rural Liberia. *Journal of Global Health Reports*. 2021;5:e2021073. Available at: https://www.joghr.org/article/25979-improvements-in-malaria-testing-and-treatment-after-a-national-community-health-worker-program-in-rural-liberia

[159] Zulu, J. & Perry, H. (2021). Community Health Workers at the Dawn of a New Era. Health Research Policy and Systems. Accessible at: https://health-policy-systems.biomedcentral.com/articles/supplements/volume-19-supplement-3

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.

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
Community IPTp	MiP
Community-based ITN distributions	Vector Control

Many malaria prevention campaigns utilize CHWs, and the impact on their workload and ability to perform routine tasks in the context of campaigns should be considered when planning campaigns. Integration of case management services into campaigns has been rolled out in several countries and can also be considered in campaign planning.

Integrated Community Case Management

Because timely access to quality case management remains inadequate in most countries with high childhood mortality, especially during the most critical first 24 hours after symptom onset, integrated community case management (iCCM) is an equity-based approach which aims to increase access to care at the community level for the hardest to reach populations. The iCCM approach provides standard integrated management of childhood illness (IMCI) 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 identifying danger signs and facilitating referral of complicated and severe malaria, including possibly the use of pre-referral rectal artesunate (RAS).

Numerous studies[160] 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[161]. The iCCM program in each country should be tailored to meet country needs which include decisions on location of CHWs, number 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 aged less than 5 years, as well as malaria community case management (mCCM) in older age groups where country policies allow (e.g., Rwanda, Senegal, Ethiopia, Thailand, Cambodia, and others) . There is considerable evidence that mCCM of all ages is feasible and increases timely access to malaria services. As such, PMI is currently supporting operational research on the expansion of age ranges for mCCM in two countries to understand some of the implications and help inform expansion of mCCM to all ages. Please see mCCM for all ages section below for more information.

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

- Integrated training and supervision
- 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 [162] for CHWs implementing iCCM/mCCM (see details in the systems section of this document and the FAQ document on the 2021 policy shift on the payment of salaries and stipends)

[160] Smith Pantain et al. (2014) Community Health Workers and Stand-Alone or Integrated CAse Management of Malaria: A Systematic Literature Review. AJTMH 91(3). https://www.ajtmh.org/view/journals/tpmd/91/3/article-p461.xml?tab_body=abstract

[161] https://www.who.int/publications/m/item/an-equity-focused-strategy-to-improve-access-to-essential-treatment-services-for-children

[162] As per the ADS, 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 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

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 (note that Global Fund has changed their policy to include this support if requested in the 2023-2025 funding cycle)

PMI country teams should work with local partners to support iCCM whenever possible and actively engage with Maternal and Child Health (MCH) 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. In a recent policy shift, the Global Fund will now allow countries to decide to fund, through the grants in the 2023-2025 funding cycle, the procurement of non-malaria iCCM medications for children under 5 where malaria case management and iCCM are provided by CHWs. This includes antibiotics for pneumonia and oral rehydration salts and zinc for diarrhea. Funding for non-malaria iCCM medications would typically come from malaria or RSSH grants, however funding could come from any Global Fund grant as is appropriate for a country's specific implementation of iCCM. Please refer to Annex 3 of the Global Fund RSSH Information Note and the CHW Programmatic Gap Table for more details. More resources for iCCM, including tools, reports, articles, and event materials, can be found in the iCCM hub on the Child Health Task Force website.

Malaria community case management for all ages

The documented success and acceptance of iCCM for children under five has led to increasing interest in expanding access for malaria community case management (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). The primary example of recent expansion of CCM to all ages comes from Rwanda, which officially expanded mCCM to all ages in 2015 (along with other policy changes aiming to reach the unreached, such as making malaria diagnosis and treatment services free for the lowest socio-economic categories of the population) and is one of the few countries that have conducted and published an assessment of the impacts of *changing* this policy, looking retrospectively at routine data[163]. A PMI-funded OR study is currently underway in Malawi to formally assess the resource needs and impacts of expanding access to mCCM all ages in order to

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)

[163] 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, Accessible at: https://doi.org/10.1093/trstmh/try093

inform policies and implementation in other countries. A similar study was also conducted in Madagascar, and results are forthcoming. 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 (Ashley Malpass, Dean Sayre, and Laura Steindhardt) to discuss the benefits and potential logistical considerations of such a strategy within the national context if such a policy change is being considered. For countries that are moving toward new implementation of mCCM for older age groups, it is important to consider how such an expansion will affect the commodities needed at the community level, taking into consideration that CHWs will test and treat some cases that would have otherwise been treated at health facilities but will also be identifying cases that would have otherwise gone untested and untreated. It is recommended to make adjustments to data and logistics systems to allow for age-specific data to inform these changes and to also closely monitor changing stock needs as the older age groups are included. Teams may also consider pre-positioning stock intended for older age groups as the age expansion is first rolled out.

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 targeted communities. 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. This approach has some evidence that it is feasible and effective, both as a means of reducing severe disease and death and as a transmission reduction strategy, in other settings. It also can be viewed as a strategy for primary health care and community health system strengthening, since it has the potential to help supervision, supply chain, and community care-level care seeking also become more proactive. There is also qualitative evidence that ProCCM has been highly appreciated by the health care workers in the health facilities since it significantly reduced their workload and that the proactive sweeps can lead to better supervision, supply chain monitoring, and community engagement through improved visibility and accountability of community health services.

The most well-established example of ProCCM is the PECADOM Plus program in Senegal. In this program, CHWs are paid to conduct weekly visits to all households in their catchment areas during the seasonal 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.[164] This approach, started in the highest transmission districts, was scaled to 40 of Senegal's 76 health districts by 2016, including higher transmission areas within zones of low-moderate transmission. Current efforts extend the period of implementation and increase the proportion of communities (both geographic and other pockets of unreached, such as children living in group settings) benefiting from this intervention.

Results from a study in Madagascar suggested that ProCCM was associated with decreased parasite prevalence among all ages[165]. 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 (some PMI funding) with final results expected in 2023, 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 case management 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: Annē Linn, Julie Thwing, and Laura Steindhardt. 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 community sweeps.

Severe Malaria Treatment and Referral

Successful treatment of severe malaria can often depend on a complex cascade of decision-making and interactions involving caregivers/patients, CHWs, and referral health facilities. Although there are many ways to visualize this pre-referral and referral pathway, one example is shown in the figure below. CHWs' role in managing severe malaria consists of recognition of danger signs/severe disease,

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

[165] Ratovoson, Rila, et al. "Proactive Community Case Management Decreased Malaria Prevalence in Rural Madagascar: Results from a Cluster Randomized Trial." BMC Medicine, vol. 20, no. 1, Oct. 2022, p. 322. BioMed Central, https://doi.org/10.1186/s12916-022-02530-x

administration of pre-referral treatment if policies allow, and rapid referral within 24 hours to appropriate health facilities for parenteral treatment followed by a full course of artemisinin-based combination therapy (ACT).

Figure 4: Continuum of care for an episode of severe febrile illness (central block) and key themes identified for analysis

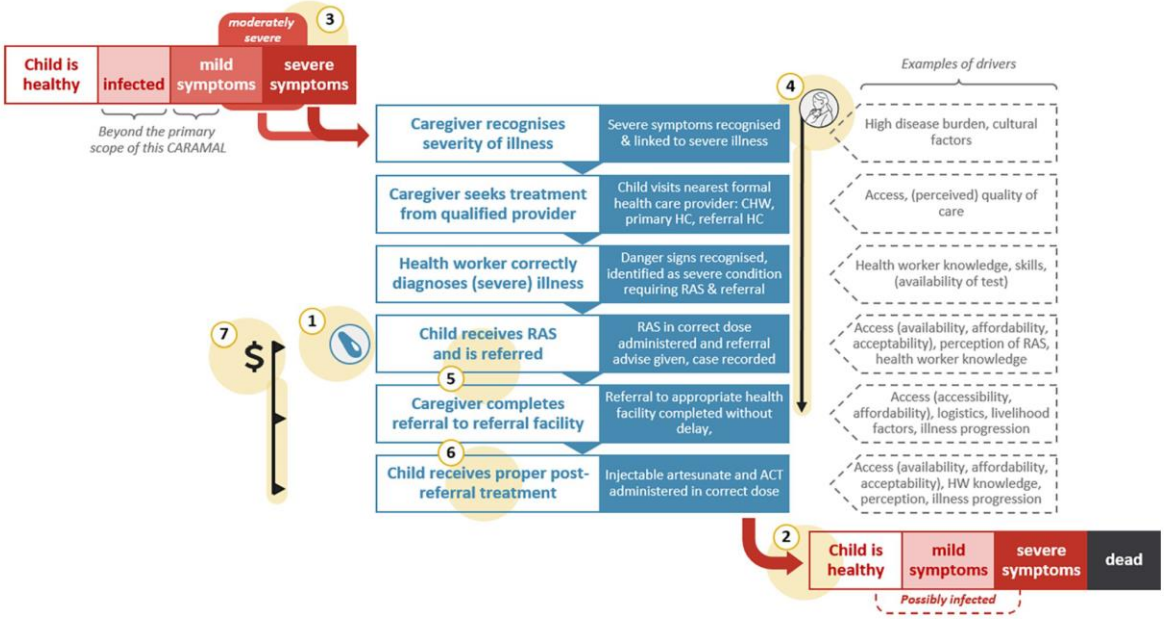


Fig 3. Continuum of care for an episode of severe febrile illness (central block) and key themes identified for analysis (numbered with yellow highlights). 1. RAS implementation (coverage), 2. Health impact of introducing pre-referral RAS, 3. Severity of illness, 4. Treatment seeking pathways, 5. Treatment and referral at community-based providers, 6. Case management at referral facilities, 7. Cost and cost-effectiveness of introducing RAS.

Continuum of care for an episode of severe febrile illness copied from Lengeler et al., 2022

At the start of the pathway, many factors can influence the initial care-seeking of caregivers, including recognition of disease severity and access to health care, which may depend on adequate transportation, financial resources, time, and the health care providers available (e.g., CHWs, lower-level health facilities, private sector facilities). When CHWs are the initial points of care, then they need to be able to correctly classify a patient as having severe malaria. 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.

In many countries, pre-referral rectal artesunate (RAS) can be administered by CHWs (building off of the iCCM platform) to manage severe malaria, with timely and effective referral, in children aged 6 years or less. See the Case Management section for dosing guidelines.

The UNITAID-funded CARAMAL (Community Access to Rectal Artesunate for Malaria) operational research study in Nigeria, Uganda, and DR Congo, which aimed to inform strategies for RAS

implementation and scale-up, showed that large proportions of children in the study areas were not provided the correct RAS dosage. Efforts should be made to ensure that where RAS is implemented, CHWs (or referring providers) are adequately supplied with the commodity and trained on its administration. Results from CARAMAL also 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. Timely referral is crucial following the administration of RAS, as pre-referral treatment alone is not a substitute for proper 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.

Successful at-scale strategies to improve the referral system at the community level for severe malaria are not well documented and depend on the local context. Some studies have shown that facilitators for referral can include having referral guidelines in place, using referral slips, having patients receive "expedited" treatment so they do not wait in lines at the referral health facility, and good communication between CHWs, supervisors, and referral health facility staff.[166, 167] Additionally, PMI has supported strategies to improve referral, such as community involvement and emergency transport services in Zambia. Strengthening referral systems must also be accompanied with adequate quality of care and commodity stock at referral health facilities. For more information on the management and referral of severe malaria cases, please see the Case Management section.

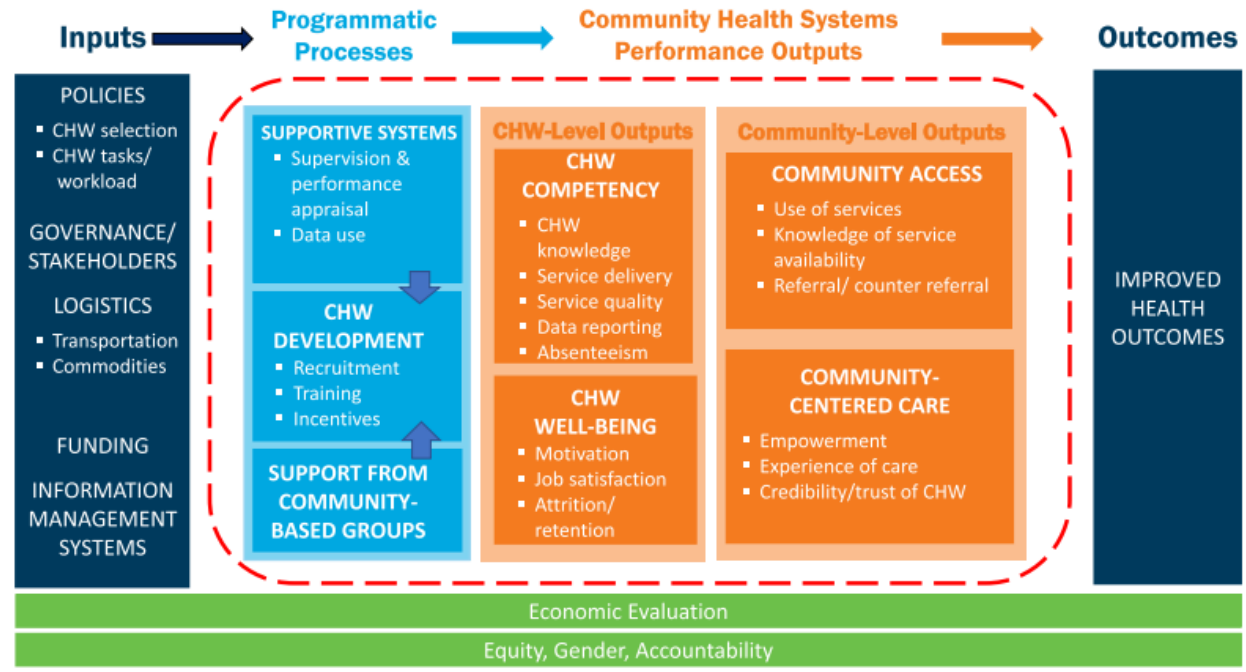
Quality of Care

Optimizing the quality of care provided at the community should orient all aspects of a CHW program, including selection and training of CHWs and monitoring and evaluation 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 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 competency is the CHW's adherence to the standards and procedures of his/her tasks.

Figure 5: Community Health Worker Performance Measurement Framework

[166] LeBan et al. Community health workers at the dawn of a new era: 9. CHWs' relationships with the health system and communities. Health Res Policy Sys 2021, 19(Suppl 3):116. https://doi.org/10.1186/s12961-021-00756-4

[167] Give et al. Strengthening referral systems in community health programs: a qualitative study in two rural districts of Maputo Province, Mozambique. BMC Health Services Research (2019) 19:263. https://doi.org/10.1186/s12913-019-4076-3



Community Health Worker Performance Measurement Framework copied from 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 related to selection, skills, supervision, supply, and salary. For example, the quality of CHW services is strongly influenced by the level of functioning of 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 monitoring and evaluation of CHWs services.

It is important to monitor the quality of care provided by CHWs 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, 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). A quality improvement framework specifically for CHWs is under development and will be shared once it is finalized in mid-2023. 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 stand-alone survey or integrated into health facility surveys and/or as clinical vignette assessments[168]. For example, health facility surveys 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: Rose Zulliger and Dean Sayre.

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 through interpersonal communication and provide health services.

As PMI intensifies efforts to strengthen community health platforms, supporting CHWs to deliver effective SBC - either during their routine case management 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 and impact 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 trainings 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 complimentary information.

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

[168] 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. Available: https://www.ghspjournal.org/content/9/Supplement_1/S111

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 case management or other health services and/or discuss the health of household members. CHWs can include malaria SBC in home visits 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 and supervised 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

When service delivery and SBC programs combine efforts, they can improve health outcomes. Yet service delivery and SBC programs often operate in silos. To facilitate improvements with demand for services with service provision, it is essential for SBC and service delivery partners to coordinate efforts. 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 Quality of Care section of this chapter), SBC and service delivery coordination is also important in this domain. The behaviors of CHWs and health system actors (e.g., supervisors, facility based staff, MOH staff, stock managers, etc.) who interact with CHWs, and community members are influenced by behavioral determinants, including attitudes, response efficacy, social norms, perceived

self-efficacy, risk perception, and knowledge. For example, the behavioral patterns of CHWs and supervisors during their interactions may deter from or add to the CHW's work and in turn influence the quality of care delivered and received. Moreover, multiple levels of influence, as seen in the Provider Behavior Ecosystem (found in the Blueprint for Applying Behavioral Insights to Malaria Service Delivery) affect behaviors of and relationships among CHW and other actors, including the individual, peer, community, facility, organizational, and health system levels. When service delivery and SBC programs combine efforts, they can improve health outcomes, yet service delivery and SBC programs often operate in silos. One reason has been a lack of understanding of concrete ways in which SBC interventions can support and integrate with service delivery efforts. For additional information on how service delivery and SBC partners can coordinate efforts to address provider behavior change (facility and community based) 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 community case management 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.[169] There have been a number of cases in PMI partner countries of initiatives successfully building off of malaria-focused CHW programs.

[169] 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). https://doi.org/10.1186/s12961-021-00755-5

Leveraging existing CHWs can support national preparedness and response efforts and Global Health Security. In West Africa during 2014, CHWs were able to rapidly pivot to respond to the Ebola outbreak. CHWs were uniquely positioned to educate communities about healthy behaviors such as safe burial practices and sanitation, to spot symptoms, and to conduct contract tracing and surveillance. [170] Health workers treated Ebola patients in the treatment centers but CHWs ended the Ebola outbreak by breaking the transmission chains through robust contact tracing. In several countries (Liberia, Sierra Leone, DRC) these same CHWs have been used to implement community event-based surveillance for infectious disease threats, and have identified and addressed rabies, cholera, viral hemorrhagic fevers, and others.

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 improvements of the overall health system.

Community Health Systems

USAID's *Vision for Health Systems Strengthening 2030*[171] provides the following definition of a community health system: a set of local actors, relationships, and processes engaged in producing, advocating for, and supporting health in communities and households in relation to the formal health system. Health and community systems are dynamic overlapping systems that independently contribute to improving health[172].

This section 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.

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

[171] https://www.usaid.gov/sites/default/files/documents/USAID_OHS_VISION_Report_FINAL_single_5082.pdf

[172] Further information on USAID's approach to health systems strengthening, including strengthening community health systems, as it relates to priority global health goals can be found at https://www.usaid.gov/global-health/health-systems-innovation/health-systems-strengthening

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 integrated community case management (iCCM) to end preventable child deaths: a technical consultation and country action planning, 22-26 July 2019, Addis Ababa" provided the following policy recommendations for consideration [173]:

1. Integrated community case management (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 programmes 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 community health workers (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.

[173] Institutionalizing integrated community case management (iCCM) to end preventable child deaths: https://apps.who.int/iris/bitstream/handle/10665/333541/9789240006935-eng.pdf

5. The ministry of health should have full responsibility for planning, implementing, monitoring and evaluating iCCM by ensuring coordination among community health, child health and malaria control programmes, 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 programme 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 NMP, PMI teams are recommended to work alongside their USG and NMP 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 health system strengthening 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 are a key

challenge[174]. 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, such as negative impact on care seeking at the health facility level. 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.[175] :

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 health systems strengthening are the 5 Ss: selection (also related to another S: saturation), skills, supervision, supplies, and salaries[176]. All 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[177]. Considerations for each "S" are detailed below.

[174] Koya, A. et al. The role of governance in implementing sustainable global health interventions: review of health system integration for iCCM of childhood illnesses https://gh.bmj.com/content/6/3/e003257.full

[175] 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). https://doi.org/10.1186/s12961-021-00749-3

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

[177] For more information see another set of 5 S's of health system strengthening and USAID's own HSS vision: https://www.usaid.gov/global-health/health-systems-innovation/health-systems/Vision-HSS-2030

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

Of note, 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 2000 people per CHW, for example). 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.

In the 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[178] 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;

[178] https://www.unicef.org/documents/implementation-support-guide-development-national-georeferenced-community-health-worker

- 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)[179] 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. One example of involvement of the government health system/facilities is the creation of a CHW "internship" curriculum, where trained CHWs spend time at a facility, working closely with clinicians to improve their skills. Additionally, the method of delivering continuous training should be considered, with digital tools (virtual training modules) 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 malaria case management. 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 aides; and integrated supervision visits. The 'integrated' piece of community case management 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

[179] https://www.usaid.gov/sites/default/files/documents/1864/CHW_AIM_Updated_Program_Functionality_Matrix_2018_508_final.pdf

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 standard operating procedures/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. There are also benefits, and challenges, to conducting integrated supervision visits with other health programs. Ensuring that supervisors have received appropriate training (in terms of technical training 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 CHW supervision vary across countries, with some supervision occurring in the communities where CHWs work and others taking place at the CHW-linked health facility. 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 (ex: Ethiopia) or a dedicated clinical supervisor cadre (ex: Liberia) which may improve proficiency in malaria testing/treatment; through peer supervision (ex: 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). PMI's OR/modeling prioritization process has identified operational research 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 regularly
- 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. % of correct malaria diagnoses made by a CHW)
- Incorporate data review and resupply, as appropriate
- Be supportive and non-punitive
- Be conducted by supervisors who are trained on tasks completed by CHWs 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 to assure 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 sustainable 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 community health workers.

Key considerations for community level supply chains include:

- Appreciate that every community health worker is a discrete stock holding 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 focussed 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 logistics management functionality. See 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.
- Monitoring of supply chain performance at community level is often compromised by absence of data. Routine data are often not available and monitoring tools such as EUV have historically ignored the community level. A number of countries are adapting the EUV tool to include a sample of Community Health Workers (e.g. Burkina Faso). PMI is also working on a standardized CHW module for the EUV, and countries are encouraged to incorporate this module into their EUV planning. 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."

In June 2021, PMI officially announced a change in policy regarding use of PMI funds for payment of Community Health Worker (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 malaria case management services. PMI has been continuously updating a comprehensive FAQ document as we learn from experiences implementing this policy in partner countries. This technical guidance provides a summary, and teams are encouraged to refer to the FAQ document for more details.

This guidance is intended to prompt thoughtful and realistic planning. Key points on the new policy are listed below:

- This change in PMI policy is consistent with USAID policy in the ADS and WHO recommendations on salary payments, 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 aligned 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 community case management 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 case management of malaria from case management 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 MCHN 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 groups 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 payments of CHWs the following pieces need to be considered and incorporated into strategic discussions and planning:

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

Given the complexities of country contexts and CHW programs, the consideration and operationalization of the pieces listed above may vary by country. Please reach out to the CH team if there are any questions or concerns about any of these pieces.

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 case management 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% of malaria cases in some PMI countries (ex: 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 case management, 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 TWGs
- Creating mechanisms for timely 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 stock-outs 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 country support.

Figure 6: Key Questions Addressed by the Implementation Fidelity Initiative

KEY QUESTIONS ADDRESSED BY THE IMPLEMENTATION FIDELITY INITIATIVE

Program includes Community Health Assistants (CHAs) and Community Health Services Supervisors (CHSSs)

	Recruitment	*Training*	*Supply Chain*	*Supervision*	*Incentives*	*Service Delivery*
CONTENT	Is recruitment carried out per national guidelines (literacy test, etc.)?	Are all modules in the national curriculum appropriately covered during trainings?	Are the correct drugs being supplied to CHSSs and distributed to CHAs?	Do CHSS and CHA supervision activities include all required components (e.g. patient audit)?	Are CHAs and CHSSs receiving the correct amount of monetary incentive?	Are CHAs correctly treating and referring patients per the iCCM protocol? Are CHAs correctly delivering the set of preventative services for which they are responsible?
COVERAGE	Are CHAs recruited from all communities >5km from a health facility?	Do all recruited CHAs attend each training?	Do CHAs consistently have all commodities in stock? Which commodities stock out the most frequently?	Do all CHAs and CHSSs equitably receive supervision, regardless of their location of assignment?	Are all CHAs and CHSSs receiving incentives?	Are all community members equitably receiving services from CHAs?
FREQUENCY	Does recruitment occur at the intended frequency (i.e. initially, and following CHA attrition)?	Do trainings occur at the intended frequency (i.e. initial trainings + refreshers)?	Do CHAs receive the correct number of restocks per month based on the National Supply Chain Standard Operating Procedures?	Do all CHAs receive field-based supervision twice per month? Do all CHSSs receive monthly supervision from facility- based Office In Charges? What proportion of time do CHSSs spend in the community versus in the facility?	How often do CHAs and CHSSs receive their monthly incentives on time?	Are CHAs consistently present in the communities that they serve?
DURATION	Is the rate of CHA recruitment sustained over the long-term?	Do trainings occur at the intended frequency (i.e. initial trainings + refreshers)? Does each training module last as long as it is supposed to?	How does the content, coverage, and frequency of the supply chain change over time?	How does the content, coverage, and frequency of CHA supervision change over time?	How does the performance of the incentive system change over time?	How does the content, coverage, and frequency of CHA service delivery change over time?

Figure 6: Government of Liberia's Implementation Fidelity Initiative to track the performance of systems to support its National Community Health Assistants (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.

Additional Resources for Monitoring Community Health Systems

In addition to the use of routine data for monitoring community health worker services, there are a number of global resources for the monitoring and evaluation of community health services and systems.

- CHW Assessment and Improvement Matrix (AIM): Toolkit for conducting assessment and improvement for community health worker practice
- Conceptual framework for measuring community health workforce performance within primary healthcare systems: Paper detailing a framework, list of indicators and measurement considerations for monitoring CHW performance.
- Guidance for community health worker strategic information and service monitoring: Guidance outlining a set of standardized indicators collected by CHWs on their activities and on the communities they serve.

Digital Community Health

The digitalization of systems, processes, and information has revolutionized all facets of daily life across the world. Not only are there an ever increasing number of tools being developed that introduce new functions and capabilities possible with digitalization, 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 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. 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.

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 Community Health team in 2021 to ensure it is aligned with PMI's programming and to avoid creating a technology-driven silo.

Vision: Strengthen quality health at the community level[180] 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 case management (*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 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. This resulted in country-specific follow-on activities that were prioritized by NMPs and PMI. It is recommended that the priorities identified in these assessments continue to inform use of MOP funding for incorporation of 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 new activities for MOP 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 and in the digital evolution of each country.

[180] 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.

- 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 case management and data collection support, and for systems supporting CHWs, including supervision, performance management and supply chain management
- Create a roadmap for systematic strengthening of capacity for eHealth that includes community health workers and works along the continuum of health care service delivery
- Develop a national rubric for the assessment of digital community tools to adopt in-country, considering country specific context and sustainability.
- Measure and evaluate the impact of 3-4 existing digital tools that have been deployed to determine which tool(s) to take forward at scale
- Provide support to establishing interoperability between digital community platforms and national health information systems
- Work with local government and others to establish the architecture for a community health information system (CHIS) and support planning and implementation of the architecture, ensuring it aligns with a national enterprise architecture
- Build out key reusable architectural components that will support the CHIS (*e.g.*, registries, terminology service, interoperability layers)
- 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[181] that align with the in-country architecture and NMP priorities to support community case management 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 case management and data use
- Create and implement IT skills building curriculum to support placement of IT staff to support hardware and software needs for community health programs

[181] 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."

- 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

A global report was developed to identify cross-cutting learnings from all PMI partner countries based on the foundational assessments. This can also be utilized to inform future activities.

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.[182]
3. Build and expand upon systems that already exist in-country instead of investing in separate, parallel systems.
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

[182] 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.

5. Digital technology must be used responsibly by: 1) Prioritizing the rights of host governments and individuals to consent, privacy, security and ownership when using data to accelerate malaria control and elimination efforts and 2) Implementing values and practices of transparency and openness.
6. Ensure adherence to best practices established in the USAID-endorsed Principles for Digital Development and Principles of Donor Alignment for Digital Health

PMI HQ staff (Nathaniel Moller or Dean Sayre) are available to answer questions and discuss potential activities and projects with country teams.

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

Keeping community-based malaria services resilient

Keeping malaria services resilient, a key focus of PMI's 2021-2026 strategy, has direct overlap with the focus on strengthening community health systems in many contexts. In 2020, all 27 PMI partner countries faced malaria service disruptions due to a wide range of emergencies and health systems shocks[183] (COVID-19, climate change, and security issues).

USAID defines resilience as "the ability of people, households, communities, countries, and systems to mitigate, adapt to, and recover from shocks and stresses in a manner that reduces chronic vulnerability and facilitates inclusive growth."

Pillars of USAID framework for health system resilience:

1. Preventing: systems, activities, and resources that can be used to assess existing plans, provide early warnings, avoid, and mitigate impacts of potential threats to reduce vulnerability of communities and health systems.

[183] https://d1u4sg1s9ptc4z.cloudfront.net/uploads/2021/10/10.04Final_USAID_PMI_Report_50851.pdf

2. Detecting: systems, policies, guidelines, and activities that can detect early warning, gather information, identify cases, and initiate responses.
3. Responding: activities and guidelines that can mitigate impacts of threats, control outbreaks and incidents, and save systems and lives.
4. Recovering:
    a. Restoring health system functions: resumed operations and stabilized economic, workforces, and services plans.
    b. Community strengthening: ensuring increased awareness to risks and shocks, and quality of health post emergencies

CHWs are a critical part of ensuring the continuity of service delivery, and of reaching affected populations in different contexts, along with pandemic response (prevention, education, case tracking, and screening)[184]. At the same time, there are many challenges to resilient health systems at the community level:

- The emergency workforce varies by country; pandemic detection and response plans often rely on CHWs, yet many of these cadres are not institutionalized, not well incentivized, and not trained on these tasks [185].
- There is a lack of guidance on community case management in humanitarian settings, how to coordinate with humanitarian health clusters, and safety protocols for CHWs
- CHWs can be among the affected-populations and may be forcibly displaced during conflicts.

In the face of these challenges there are number of activities that can be considered for keeping community-based malaria services resilience during shocks and stressors:

- Train and educate community health workers as first-line respondents to emergency settings[186].
- Build on existing eLearning and other training resources to better prepare CHWs to detect and respond to risk factors, symptoms recognition, and safety protocols in emergency settings
- Strengthen surveillance systems and train CHWs in febrile illness management and misclassification[187].
- Strengthen digital health and data reporting at community and health facility levels.

[184] https://www.globalhealthdelivery.org/case-collection/concept-note/community-health-workers
[185] https://www.ghspjournal.org/content/ghsp/10/2/e2100648.full.pdf
[186] https://www.ghspjournal.org/content/ghsp/10/2/e2100648.full.pdf
[187] https://amref.org/blog/community-health-workers-champion-kenyas-covid-19-response/

COMMODITY PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

New/Key Messages

PMI's supply chain was, and continues to be, adversely affected by COVID-19 and other disruptions resulting in production and logistics delays. Although global supply chain pressures have been decreasing in 2022, they remain at historically high levels and we anticipate that the supply chain will continue to be constrained in 2023. Countries should place orders early to account for longer lead times detailed in the updated Average Lead Time Table and adjust supply plans to keep inventory levels closer to their maximum level.

Countries should use the updated Commodities Costing Table, which reflects the latest freight and commodity costs. This applies to reprogramming MOPs as well. PMI is seeing a price increase across multiple pharmaceutical categories, including AL and ASAQ, as well as all ITNs. These cost increases are driven by increases to both the commodity and freight costs.

To help facilitate financial management under the NextGen Supply Chain Program Suite of Awards, PMI will begin using the Working Capital Fund, starting with FY2022 funding. All supply chain funding for centrally managed awards will be obligated to the Working Capital Fund then sub obligated to individual awards as funding is required. This will facilitate the reprogramming flexibility that countries have benefitted from under the previous programs, where the majority of funding is under one award.

PMI and other Global Health programs of USAID recommend the use of the Quantification Analytics Tool (QAT) tool for forecasting and supply planning as a replacement for the Quantimed (for forecasting) and Pipeline (for supply planning) applications. If a national malaria program does not endorse the use of QAT for either the forecasting or supply planning modules, PMI still requires its IPs to create/submit supply plans in QAT so that they are available to PMI.

PMI will procure parasite lactate dehydrogenase (pLDH) RDTs in areas which have exceeded the WHO threshold for histidine-rich protein 2 (HRP2)[188] deletions (e.g., Ethiopia).

[188] 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 *hrp2* and/or *hrp3* gene deletions, which limits the sensitivity of these tests resulting in false negatives. WHO recommends using pLDH tests in areas that exceed 5% of *hrp2* gene deletions.

PMI will procure single point-of-care RDTs with individual buffer vials only in countries pursuing national or subnational elimination with relevant low-incidence areas as identified by the Elimination Technical Team (these countries currently include Burma, Cambodia, Thailand, Laos, Ethiopia, Kenya, Madagascar, Senegal, Zambia, Zanzibar, and Zimbabwe). All PMI countries interested in smaller pack sizes may consider procuring hospital 10-packs of RDTs.

The End Use Verification (EUV) tool is being updated with a community level module that countries conducting the EUV will need to include.

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. 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 NMP adoption, tafenoquine and SD Biosensor's Standard G6PD tests can be procured by PMI. As with the roll-out 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 NMPs 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 updated Commodities Costing Table, the cost of commodities includes the costs of goods plus estimates on freight, in-transit insurance, clearance, required quality assurance testing and supply chain surcharge. *Note that the reference price used by Global Fund is based on the commodity cost only.* When preparing order requests, 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 and build in the additional funding to the appropriate partner if needed. **Countries must take into account the specific procurement lead times for the commodity they are procuring, some of which are currently over 12 months.** The lead times, which start with the receipt of a Requisition Order, include, among other steps, order processing, production, quality assurance testing, shipping and customs clearance. (Please reference the **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 seasonal malaria chemoprevention), drugs for severe malaria, other malaria pharmaceuticals (e.g., chloroquine and primaquine tablets), laboratory equipment, microscopes and supplies for microscopy, RDTs, insect repellents, 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., Malaria Indicator Survey) do not fall within the scope of PMI's malaria commodity procurement partner and alternative arrangements should be made. Please contact the GHSC-PSM TO2 COR as soon as possible when discussions around the procurement of these malaria-related commodities for national surveys begin. Please also consult the **S&I** 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 a minimum, be on the WHO Prequalification (PQ) list of Prequalified Vector Control Products to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to label claims, past performance, financial viability, and programmatic consistency to qualify ITN products for PMI procurements. For details on PMI's ITN procurement policy consult the ITN chapter. ITNs have both a shelf life and anticipated lifespan of use. These are distinct, but related attributes. Shelf life may be conveyed via inclusion of an expiration/expiry date on the ITN packaging. An ITN's shelf life is the length of time, under ideal storage conditions, that the manufacturer claims the product can remain in the packaged state without degradation. Shelf life claims vary between ITN brands and range between 24 and 48 months. The manufacturing specifications required of WHO PQ are expected to produce ITNs with an anticipated lifespan of use of 3 years and 20 washes based on WHO standard washing procedures.

An ITN can be put into use up until the maximum shelf life is reached and still be expected to maintain product integrity sufficient to meet its anticipated lifespan. ITNs packaging is expected to always indicate the manufacturing date. However, an ITN package may not necessarily include information on it, such as an expiration date, that enables the determination of remaining shelf life. If, based on the manufacturing date, there are concerns about the remaining shelf life of ITNs yet to be distributed, please contact your supply chain backstop.

Currently, there are over 20 PQ-approved ITNs, but not all meet PMI's requirements for demonstrated community effectiveness. This list includes many single-pyrethroid ITNs, six PBO 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.

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 New Nets Project co-payment mechanism. However, production capacity remains constrained.

Prior to the development of FY 2018 MOPs PMI had procured over 20 different variations of single-pyrethroid ITNs across dimensions, shape, color, and material. The variation had 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.[189] 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 leads to cost and time savings and reductions in supply chain risk. 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.

[189] 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)

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 PMI and National Program logos, standard language (in a locally appropriate script) (e.g., not for retail sale), and the GS1 barcode.

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, in the form of a MBS, durability monitoring publication, or textile use report 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, sunlight, or moisture than individually packaged nets. This exposure can impact both the shelf-life prior to being distributed and the anticipated lifespan of the ITN once in possession of beneficiaries. 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 wants to deviate from these standard specifications and 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

PMI procures a range of antimalarial medicines, consistent with WHO malaria treatment and prevention guidelines (as well as aligned with IMCI guidelines under PMI's iCCM rubric). Medicines procured by PMI requires *either* an approval through a stringent regulatory authority (SRA)[190] (such as the US FDA) or the WHO PQ Program except under exceptional circumstances which include a particular need that cannot be met by the eligible products.[191] Stringent regulatory authorities employ a robust drug dossier review to consider the safety, efficacy, and quality of pharmaceuticals intended for human use.[192] PMI also procures WHO PQ medicines 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 and prevention of malaria applies a robust dossier and manufacturing site review process, resulting in approved products of known quality, safety, and efficacy.[193]

WHO currently recommends six ACTs: artemether-lumefantrine (AL), artesunate-amodiaquine (ASAQ), artesunate-sulfadoxine/pyrimethamine (AS-SP), artesunate-mefloquine (AS-MQ), dihydroartemisinin-piperaquine (DP), and pyronaridine/artesunate (AS-PY). The market is heavily consolidated around AL, which has begun to show reduced efficacy in several countries. PMI is working with partners to support countries in diversifying their ACTs, including efforts to lower the price of AS-PY and DP, which are currently 3-4 times more expensive than AL. See Case Management section for more details.

Currently, there are three ACT products approved by a stringent regulatory authority: Novartis' Coartem® (AL), Alfasigma's Eurartesim® (DP), and Shin Poong's Pyramax® (AS-PY). 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, ASAQ, and DP (including dispersible formulations) have been approved by WHO PQ and therefore added to the WHO prequalification list[194] over the recent years. This includes two African-based manufacturers of AL, one based in Kenya and one based in

[190] Currently, the drug regulatory authorities of the European Union, Japan, USA, Canada and Switzerland have implemented International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and are considered stringent regulatory authorities. There are also various industry organizations from the aforementioned countries who hold SRA status, and some member states with observer status. For more information, visit http://www.ich.org/about/membership.html

[191] http://apps.who.int/prequal/query/ProductRegistry.aspx

[192] 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.

[193] 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.

[194] http://apps.who.int/prequal/query/ProductRegistry.aspx

Uganda. PMI can procure these products subjecting them to the same testing requirements as other non-SRA approved pharmaceuticals procured with PMI funds (see quality section).

There are several different fixed-dose artemether-lumefantrine oral presentations approved through the WHO PQ process: 20 mg artemether/120 mg lumefantrine (the most common formulation), 80 mg artemether/480 mg lumefantrine, 60 mg artemether/360 mg lumefantrine, and 40 mg artemether/240 mg lumefantrine. Likewise, fixed-dose oral presentations of artesunate-amodiaquine approved by WHO PQ are also available: 25 mg artesunate/67.5 mg amodiaquine, 50 mg artesunate/135 mg amodiaquine, 100 mg artesunate/270 mg amodiaquine. 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-prequalified 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 primaquine and most SP products from pre-approved wholesalers.[195] These wholesalers are routinely evaluated against internationally accepted quality assurance 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 prequalified) laboratories.

As with all commodities, please reference the Average 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;[196] as such, PMI sources most SP orders from pre-approved wholesalers.[197] The Medicines for Malaria Venture is working with several SP manufacturers

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

located in Africa to meet WHO PQ standards, one of which attained WHO PQ approval for their dispersible SP formulations in 2022.[198]

Historically, SP lead times have been lengthy. Although reductions in those times have been achieved in recent years (see the Average Lead Time Table in Commodity Procurement and Supply Chain Appendix 2 for further details), 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 national level SP needs are quantified during operational planning for IPTp, we encourage country teams to consider placing SP orders as early as possible.

As of the end of 2022, there are three WHO PQ approved dispersible SP suppliers, although PMI has yet to procure these products. Countries interested in procuring these dispersible formulations for use in IPTp should reach out to the Malaria in Pregnancy team and their supply chain backstop. For more information on dispersible SP and PMC , please refer to the Other Chemoprevention Approaches chapter.

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 at high risk for severe malaria at monthly intervals during the period of peak malaria transmission season. While historically implemented over a period of 3-4 months, recent models showing the benefits of additional coverage in certain settings have led a few countries to plan for a fifth round of SMC in targeted geographies or increasing the age range. Please refer to the **SMC** chapter for more details regarding the number of rounds, geographies and age ranges served as well as for information on pilots in countries with high SP resistance as data on the efficacy for alternative drugs are not yet available.

Over the past three years, PMI regularly procured AQ+SP for SMC campaigns in up to nine countries. At the end of 2022, there are three manufacturers producing WHO prequalified 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 additional suppliers increases production capacity but registration is still a deciding factor 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

[198] The newly WHO PQ-ed manufacturer is located in Kenya, and the other two SP manufacturers supported by MMV in the WHO PQ pipeline are located in Nigeria. Although the former's SP formulation is dispersible, the latter two are pursuing prequalification of hard tablets.

registration of all prequalified suppliers 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. **Please note that children over 59 months of age require 2 blisters per dose.**

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 the 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.[199]

If SMC is relevant to your country team and PMI is requested to procure commodities, orders should be submitted 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 prequalified injectable artesunate presentations (30-, 60- and/or 120-mg formulations). There are three WHO prequalified suppliers of 60-mg formulation, the most commonly procured. There are also three different strengths of rectal artesunate suppository presentations available (50-, 100- and/or 200-mg formulations). Only the 100-mg preparation has approval through the WHO prequalification program (through two separate vendors), and WHO recommends the use of the 100-mg rectal artesunate suppositories. For these reasons, **PMI is only procuring the 100-mg formulation**. Rectal artesunate 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 rectal artesunate suppository orders in advance,

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

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 through the WHO PQ. As demand for these products has decreased, lead time and quality issues have increased, so procurements need to be planned far in advance in order for them to arrive when needed. Please see the **Case Management** chapter for further information on the appropriate selection of injectables. Please work closely with your in-country supply chain implementing partner during supply and demand planning for these and all malaria-related commodities. For additional information regarding commodities for severe malaria treatment, please see **Appendix 3**.

Rapid diagnostic tests

PMI requires WHO PQ for *P. falciparum* and *P. falciparum/P. vivax* 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 prequalification.

An analysis of procurement data has shown that prices for RDTs that are sole-sourced are up to twice the price of the same RDT when there is open competition. An additional analysis undertaken by MalariaCare found that all countries either were using multiple brands of RDTs concurrently or had switched brands. Health workers were able to manage multiple RDT brands or switching brands without significant issues in use. Supervision and job aids supported health workers in managing the change. As such, PMI no longer allows sole source selection of RDTs based solely on health worker training concerns. The Case Management 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.

Some countries have requested smaller pack sizes than the standard 25-pack size. Based on single point-of-care RDTs (individually packaged with buffer) representing approximately a 30% higher cost compared to multi-pack RDTs, only PMI countries pursuing national or subnational elimination goals with relevant low-incidence areas as identified by the Elimination Technical Team are permitted to procure single RDTs (currently: Burma, Cambodia, Thailand, Laos, Ethiopia, Senegal, Kenya, Madagascar, Zambia, Zimbabwe, Zanzibar). Other higher burden countries desiring smaller volume RDT packaging due to various reasons (e.g. concerns for CHW attrition, convenience, etc.) could consider different multi-pack options like the 10-pack (hospital pack of 10 tests with a single buffer bottle) that are

currently priced slightly higher than the 25-pack boxes, but are priced lower than the single RDTs. For countries considering this option, please reach out to the Case Management and Supply Chain Teams for awareness, but justification will not be required at this time.

WHO has identified malaria parasites with *hrp2* gene deletions in limited areas of sub-Saharan Africa (see **Case Management** chapter for more details). Non-HRP2 based RDTs are indicated in settings with >5% reported *hrp2* gene deletions in those patients presenting with symptomatic malaria. 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 currently will not procure two line multi-antigen RDTs for *P. falciparum*.** Some manufacturers also produce a single line RDT that contains antibodies to both HRP2 and pLDH. It is hoped that this type of test might be a programmatic solution in countries with HRP2 deleted parasites in limited areas. **Countries that either have evidence of HRP2 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. PMI will consider non-HRP2 tests (e.g. pLDH tests) where appropriate. Please also refer to WHO guidance on this topic.**

Of the few stringent regulatory agency approved glucose-6-phosphate dehydrogenase (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. Supplies for TES (filter paper, laboratory reagents, etc.) can be ordered under the central supply chain mechanism. Please plan your orders far in advance (12 months) given the many nuances of these orders. See the Commodity Procurement and Supply Chain Management Appendix 2: Average Lead Time Table for more details. 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, as procurement of all available malaria vaccines will be done by UNICEF with financing from Gavi. In-country, the vaccine will be managed as part of the Expanded Program for Immunization (EPI) supply/cold chain. As the discussions on possible vaccine introduction evolve in the field, we encourage PMI country teams, in coordination with their MCH colleagues, to familiarize themselves with their country EPI program. Please see the **Vaccines** chapter for more information.

Topical Repellents

PMI will support and procure select EPA-registered topical repellents and promote their use for migrant and mobile workers in elimination settings in the Mekong. For more details on which topical repellents and further information on presentation options (size, concentration, mode of application, and hours of protection) that may be procured by PMI, please refer to the Elimination chapter. Countries supporting the introduction of topical repellents into their supply chains should apply the same guidelines for the storage, transport, and quality assurance of repellents as they currently do for other pesticides and consult PMI's Integrated Vector Management Program for Malaria Vector Control Programmatic Environmental Assessment (PEA), as well as PMI's IEE for Repellents.

Lot 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, ITNs, and select laboratory supplies. 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 standard operating procedures 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-prequalified and wholesaler-sourced products requiring compendial testing based on potential risk. For the latter group, the timing of testing – either pre-shipment or concurrent – is dependent upon PMI's 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% 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.

PMI procures laboratory supplies including reagents in select countries from eligible wholesalers that utilize robust quality assurance mechanisms to ensure that the products meet the required quality standards.

All test reports (of pharmaceutical, RDT, and ITN quality) are kept on file electronically with PMI's quality assurance 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.

Although PMI utilizes these testing strategies, some countries may choose to implement their own post-shipment QC and test products entering the country in accordance with their regulations. 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. If a country chooses to retest a product that has passed the required PMI quality controls, a PMI implementing partner will not be held liable for products that fail country testing after the product has passed the PMI QC mechanism. A product failing a country's QC testing is an insufficient threshold for PMI to automatically initiate product replacement given the nuances of testing methods for each product and inspections protocols. Nevertheless, PMI will work with each country to examine the evidence and/or to consider alternative solutions, if possible, in the case of any discrepancy.

In cases where PMI funding is used by local procurers (see "Government-to-Government Funding for Commodities" section below for required approvals), the expectation is that the same quality standards and standard operating procedures are used to procure eligible products.

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 stock outs have been a recurrent problem for country programs and may continue with potential decreases in donor contributions. PMI has observed that transition to a new Global Fund grant has posed supply risk in the past; however, urgent orders can receive advance payment before grants are finalized. If a PMI focus country will be transitioning to a new grant, the country team may consider some contingency planning for potential delays in Global Fund initial orders.

As in previous years, several PMI-supported countries have experienced difficulties with funding leading to disruptions in the supply of key commodities. In these situations, country teams should be aware that PMI directs its SC partner to hold an emergency commodity funding account that can be utilized by countries to help avert stockouts of key malaria products and maintain flexibility in commodity funding.[200] 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 AL.[201] 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 stock out and is provided with a two month supply from the stockpile stock with 50% shelf life (12 months or more remaining shelf life), this stock will be used before it expires in a year. As such, country teams are encouraged to work with NMPs 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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[200] 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.

[201] 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 do 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/Headquarters (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, country importation constraints, 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 semi-annual 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 their PMI supply chain backstop.

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. Many of the theft and diversion issues encountered by countries can not be addressed solely through supply chain technical interventions, so broad engagement with stakeholders outside of the health sector is important.

As part of their supply chain risk management, countries should identify options to mitigate the risk of loss, including regular third party monitoring, inspection of storage facilities, review of inventory records, comparison of logistics and case management data to identify significant discrepancies between reported malaria cases treated and treatments dispensed, strengthening in-country logistics management information systems or complementary systems such as track and trace, and activities to strengthen national regulatory authorities.

Central Commodity Mechanisms

While PMI currently 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). During 2023 (CY), PMI will begin transitioning to the NextGen Supply Chain Suite of Awards (NextGen). NextGen includes nine mechanisms, including the next malaria commodity procurement contract. The supply chain team has been working with PMI country teams to plan for the transition; if you need further guidance please reach out to your supply chain backstop. Additional details on NextGen can be found here.

1. Global Health Supply Chain – Procurement and Supply Chain Management (GHSC-PSM) Malaria Task Order (TO2) – The GHSC-PSM IDIQ and Malaria Task Order were awarded to Chemonics in April 2015. The malaria task order supports USAID's implementation of malaria programs through the procurement, management and delivery of high quality, safe, and effective malaria commodities; the provision of on-the-ground logistics, supply chain, and related systems strengthening technical assistance and implementation capacity; provides technical leadership to strengthen the global supply, demand, financing, and introduction of existing and future malaria commodities. PMI focus countries are required to use PMI's central mechanism for all non-IRS commodity procurement needs. The requirement (unless granted an exception) to work with PMI's central procurement agent is due to PMI's stringent quality assurance and quality control

standards for all pharmaceuticals and related commodities procured as well as some pre-negotiated contracts to obtain the best pricing, based on volume and pooling of orders. The central procurement agent also has flexibility in accommodating last minute order changes and the ability to handle in-country logistics, clearance procedures, and, if necessary, distribution needs. Their familiarity with USAID regulations and requirements is an added advantage; other procurement agents' lack of familiarity can translate into significant delays in the arrival of commodities. The mechanism's scope also covers in-country supply chain, pharmaceutical management, and logistics for malaria commodities. To further visibility and realistic budgeting, the in-country direct warehousing and distribution costs should be included as a separate line item in the MOP from both the procurement and the technical assistance activities. If you are uncertain of how to best estimate these costs, please contact your supply chain backstop.

2. UNICEF Umbrella Grant—As stated above, and only with prior approval from the U.S. Global Malaria Coordinator, PMI teams may choose to use the UNICEF Umbrella Grant to procure specific malaria commodities (e.g., ITNs for a joint campaign where UNICEF is already procuring a portion of ITNs for the campaign) where UNICEF has a country presence and is already engaged in malaria commodity procurement.

Regardless of the mechanism used, no PMI funds may be used to procure products of questionable quality.

Transitioning to the Working Capital Fund

To help facilitate financial management under the NextGen, PMI will begin using the Working Capital Fund (WCF) starting with MOP 2022 funding. All supply chain funding for centrally managed awards (technical assistance, in-country distribution, and commodities) will be obligated to the WCF then sub-obligated to individual awards as funding is required. This will facilitate the reprogramming flexibility that countries have benefitted from under the previous programs, where the majority of funding was under one award.

Despite the split between multiple mechanisms, such as the Integrated PSA, Qualifying Testing and Issuing (QuTI), and Control Tower, PMI will continue to plan their commodity procurements per commodity type under one MOP line. The Commodities Costing Table will include the fully loaded costs to account for funding required across the relevant projects. For example, the Control Tower costs will be a flat percentage applied to the commodity costs and will be evaluated on an annual basis. The quality assurance costs associated with commodity procurement will continue to be factored in as they have always been under the previous supply chain mechanisms.

Countries will only need to enter one field support entry across these mechanisms for commodity procurement, specifying the WCF. Once obligated to the WCF, the funding becomes "no year funds"

and is protected from the two year fund expiry. The PMI Supply Chain Team will facilitate the allocation across relevant projects as outlined in the MOP and based on current commodity and project specific pipelines. This will provide flexibility as commodity costs and needs change to respond to the most updated commodity requirements by adjusting the allocations between the Integrated PSA, QuTI and other relevant mechanisms on a continuous basis.

The PMI Supply Chain team will send out additional guidance when available. If you have questions, please reach out to your supply chain backstop.

Government-to-Government Funding for Commodities

In March 2012, USAID/Washington released the *Global Health Implementation and Procurement Reform Commodities Procurement Guidance* to better explain the Agency's role under the USAID Forward Initiative as it relates to the procurement of health commodities. In response to a growing interest by some countries to move toward a greater level of self-sufficiency in maintaining national health commodity supply chains, USAID/Washington may be supportive of the procurement of health commodities by host country governments through local systems. The Implementation and Reform guidance sets forth specific criteria for malaria commodities to be considered for 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 headquarters and host-country USAID Missions in order to move this new process forward while meeting all USG, PMI, Mission, and country regulations, requirements and needs. To date, only one country has met the requirements and received approval to procure with PMI resources.

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, etc. What often starts as a network of disparate global supply chains managed by different donors and procurement agencies, often converge when products reach a country's central warehouse. These supply chains rely on trading partners to share data. However, the current approach to managing and sharing supply chain information undermines the value and use of global health supply chain data. Implementing GS1 enables visibility through the supply chain in the areas of product and location identification, data capture, and master, transactional, and event data exchange. On a global level, this increases PMI's ability to maintain updated product data from suppliers. In addition, other donors such as Global Fund are looking at implementing GS1 into their supply chain, enabling smoother data exchange for the future when looking towards coordinated supply planning. GHSC-PSM is also working with suppliers for their products and packaging to be GS1 compliant, which includes a GS1 barcode for automated identification and data capture to 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 encourages country teams to support their host countries to learn more about GS1 standards, introduce a supportive policy environment and tools, and implement track and trace systems. These efforts will require tailored technical assistance, funding, and collaboration with other donor agencies.

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 NMPs, 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.[202] 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, PRH, MCHN, etc.) and where other health elements are relying on government systems, PMI investments must be coordinated with other USG health supply chain investments. 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 improvement in malaria commodity availability, PMI is continuing its approach to optimizing PMI's supply chain investments. Starting in CY 2020, PMI operationalized a Three-year Stockout Reduction Initiative to guide PMI country investments towards achieving a clear,

[202] Guidelines for Managing the Malaria Supply Chain. https://d1u4sg1s9ptc4z.cloudfront.net/uploads/2021/03/guidelines-for-managing-the-malaria-supply-chain-1.pdf

time-bound target for improved commodity availability at health facilities. Working with our implementing partner and coordinating with the Global Fund, PMI established the target to be used across PMI countries (less than 10% 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 also informed development of PMI FY 2023 MOPs and prior year reprogramming. An amendment to the playbook is now available that contains guidance for identifying the root causes of stockouts at the community level and prioritizing solutions to address them. PMI country teams are requested to keep this initiative, and the outputs of any in-country work related to it, in mind when allocating funding across all PMI interventions during the development of the FY 2024 MOPs to ensure that PMI investments will address each country's most critical issue(s) impacting commodity availability.

Health Supply Chain 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. Having effective health supply chain information systems in place is critical for obtaining and exchanging these data. Some of the systems PMI may typically invest in are those involving; commodity tracking and tracing; transportation management; warehouse management and ordering & resupply. Sometimes these systems work independently of other systems and sometimes their functionality is combined into a single, stand alone, platform.

An LMIS is the organized system of health supply chain information tools, 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 NMPs and other stakeholders to ensure the capture and consistent use of health supply chain information systems data. PMI country teams are encouraged to participate in

discussions concerning the rollout, expansion, adaptation, consistent use, and improvement of either a single health supply chain information system or 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[203] (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.[204] 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 health supply chain information systems, 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.

[203] PMI Digital Community Health Initiative Cross-Country Landscape Report

[204] eLMIS Selection Guide :Electronically Managing Supply Chain Information. https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/elmis-selection-guide-electronically-managing-supply-chain-information.pdf

- Community Health Workers (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 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). See the discussion of the community module in the EUV below.

Product Selection

In addition to epidemiologic considerations for product selection, a number of other key factors must be taken into consideration when selecting products to procure. These include whether a product is part of the country's National Essential Medicines List and is registered by the National Drug Regulatory Authority (in the absence of current registration, a waiver will be needed, and if approved, is a lengthy process that could delay arrival and distribution of commodities). Other issues to consider relate to logistics. What are the storage requirements of a product at the central, health facility, and community level? Is there sufficient capacity within the country to distribute and manage the products? Do they require a cold chain during storage and distribution? What is the shelf life of the product? Have the requisite health care workers been properly trained in the management of the commodity? PMI country teams should work with NMCPs and stakeholders to ensure both epidemiology and logistics are

considered in selecting products for the program and/or building the logistics and technical capacity to accept and appropriately use the product.

Quantification

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service) and determining when the products should be delivered to ensure an uninterrupted supply for the program. This is usually done in two steps: first, forecasting total need and then second, 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 Global Health programs of USAID 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 became 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 strengthen the capacity of the NMP 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. If a national program does not endorse the use of QAT for either the forecasting or supply planning modules, PMI still requires its IPs to create/submit supply plans in QAT so that they are available to PMI. 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[205] 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 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

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 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 sufficient 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

[205] Logistics Management Units: What, Why, and How of the Central Coordination of Supply Chain Management. https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/logistics-management-units-what-why-and-how-of-the-central-coordination-of-supply-chain-management.pdf

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. While using private mechanisms, PMI provides technical assistance to strengthen the capacity of national systems, including outsourcing and performance management, with the long term goal of transferring PMI-funded commodities into strengthened national 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 is supportive of countries' use of the private sector for supply chain.** This can improve supply chain performance, increase resiliency and sustainability, and allow the public sector to focus on its core competencies in delivery of healthcare service. 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 pre-qualified ITN supplier recommends storing their nets in containers after their delivery to procurement-defined destinations. For more details, see: Use of containers to store insecticide-treated nets: operational concerns and considerations.

Quality Monitoring

As described above, quality, safety, and efficacy issues continue to be a major concern and top priority in the procurement of all malaria pharmaceuticals. Quality is important not only prior to shipment, but throughout the supply chain and logistics cycle, through to the end user. PMI country teams should work with NMPs to ensure that QA standards are adhered to throughout the logistics cycle and any concerns are addressed.

An important component of the quality assurance continuum is post-marketing surveillance, 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 post-marketing surveillance activity. As a one-off activity, data collected will have little use, unless used to highlight an acute known or suspected problem (e.g., collaboration with USAID's OIG, for example). Moreover, there are a limited number of partners whose relevant scopes of work can accommodate these activities. Historically, PMI support toward this has focused on surveillance for both antimalarial availability and quality, in both the private and public sectors.

It is also important to distinguish post-marketing surveillance 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.[206] 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

[206] 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."

support pharmacovigilance activities may increase. When considering pharmacovigilance as part of the introduction of a newer ACT, please contact the PMI Case Management and Supply Chain Teams so that pharmacovigilance efforts may be coordinated with other donors and existing country systems and infrastructure.

Monitoring and Supervision

To ensure optimum performance, supply chain systems should be monitored and evaluated on a regular basis. PMI country teams should work closely with program managers and supply chain managers to review data across all levels of the system to improve system performance. The Supply Chain Technical Working Group or Logistics Management Unit (LMU) is a good venue to facilitate monitoring and evaluation of supply chain system performance. In addition to typical monitoring and supervisory tools recommended for all supply chains (e.g., LMIS reports, supervisory checklists, etc.), PMI uses malaria-specific tools to routinely monitor the supply chain system. 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, rectal 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 https://app.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. The PMI HQ EUV team is working with our implementing partner to develop an EUV module to assess commodity availability at the community level. This module will be required for countries with CHW programs and currently conducting the EUV and will be rolled out in CY 2023. 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 headquarters to determine if there is another tool in use in-country that provides this information or to discuss any changes in EUV methodology. Any decisions to stop the EUV and use another tool must receive approval from the PMI HQ EUV team and Agency Leads 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 Task Order Malaria (TOM) table produced by PMI's central procurement mechanism which is available online through the TOM Table Dashboard as well as through biweekly downloads distributed by the Supply Chain Team. 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)[207], 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 a 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 community health workers in supply chain

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

management. PMI country teams are encouraged to work with the NMP 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 on specific competencies (for example, 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.

Commodity Procurement and Supply Chain Management Appendix 1: Commodities Costing Table

To access the Commodities Costing Table, please navigate to the Supply Chain folder in the Technical Team Field Resource Center on the PMI G-Drive or reach out to your supply chain backstop.

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 h 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 (at a dose of 2.4mg/kg of body weight). 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 7 days (or a maximum of 9 total doses). Intravenous artesunate solution 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 (4) 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.[208] This assumes that the patient is able to swallow ACT tablets after these 3 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, 60 mg, 120mg), the proportional breakdown of treatments by age/weight, and the average estimated treatment course, which is a minimum of 3 doses and a maximum of 9 doses.

For rectal artesunate dosing, WHO treatment guidelines, third edition, recommend a 10 mg/kg pre-referral dosage. Per the October 2017 WHO information note, if using a 100 mg suppository, this would be one suppository for children 2 months up to 3 years and two suppositories for children 3 years up to 5 years. Available preparations include 50-, 100- and 200-mg capsule suppositories; however, WHO and PMI recommend 100 mg capsules. As a reminder, rectal artesunate is indicated in children less than six 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

[208] Injectable artesunate has two administration routes: intravenous (as a bolus) or intramuscular. Also of note: although there are three WHO-prequalified strengths of injectable artesunate, only the 60- and 120-mg dosage formulations are available for public sector procurement. The 30-mg dosage formulation is only offered for private sector procurement by the WHO-approved manufacturer, Guilin.

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).

SOCIAL AND BEHAVIOR CHANGE

New/Key Messages

Prioritizing Behaviors: PMI supports SBC activities that promote the uptake and maintenance of all key malaria interventions. However, to ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, PMI recommends that country teams use available data to identify approximately ***three priority behaviors for which an SBC intervention is needed***.

Malaria Vaccine: As PMI partner countries begin to introduce the malaria vaccine, PMI country teams may be asked to support malaria vaccine introduction. One way that PMI can support the introduction of the malaria vaccine is through SBC. The PMI SBC Team and the USG Malaria Vaccine Implementation Working Group are contributing to the development of global malaria vaccine SBC guidance which should be available in 2023.

SBC for *An. stephensi*: 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 guidance is expected to be available for dissemination in early CY2023 and will include identifying human behaviors currently being promoted or proposed to reduce *An. stephensi* populations. Further, this guidance will include SBC recommendations by invasion status (e.g., where *An. stephensi* has been identified; high and low risk of invasion) and malaria transmission setting.

Malaria Behavior Survey (MBS) Low Transmission Questionnaire: The MBS tool has been adapted for implementation in low-transmission settings through coordinated efforts between the SBC and Elimination Technical Teams and is available at malariabehaviorsurvey.org.

Introduction

Achieving and maintaining PMI and National Malaria Program (NMP) goals depends on the acceptance and correct and consistent use of proven interventions (e.g., ITNs, IRS, RDTs, ACTs, IPTp, and

chemoprevention). When tailored to specific country contexts and needs, social and behavior change (SBC) activities play a critical role in promoting uptake of these interventions and achieving desired individual and public health impacts. Thus, to improve the overall quality of malaria control efforts that contribute to reductions in morbidity and mortality, PMI supports a range of SBC activities to increase uptake and correct and consistent use of key interventions.

Key Areas of PMI Support for SBC

Key areas of PMI support for SBC include: (1) capacity strengthening, (2) design and implementation, (3) coordination with service delivery, and (4) monitoring and evaluation.

Capacity Strengthening

To ensure sufficient host country capacity for malaria SBC activities, PMI supports capacity strengthening efforts for individual, organizational, and systems level activities related to the design, implementation, and monitoring and evaluation of SBC activities. SBC capacity strengthening activities should be directed toward individuals, organizations, and systems involved in SBC design, implementation, and monitoring and evaluation at the national and sub-national level, including NMP and MOH staff, national and sub-national SBC technical working groups, and local organizations. .

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 NMP and Ministry of Health staff in global and regional meetings (e.g., International SBCC Summit and RBM Partnership to End Malaria SBC Working Group Annual Meeting) and technical organizations such as the RBM Partnership to End Malaria Social and Behavior Change Working Group.[209] PMI also strongly encourages engagement in online collaboration fora, such as the Springboard for Health Communication Professionals.[210]
- **National and Sub-National Malaria SBC Technical Working Groups:** Given the cross-cutting nature of SBC, a national-level malaria SBC technical working group is critical. Such a

[209] 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.

[210] https://springboardforsbc.org/

group facilitates information sharing and strengthens an NMP's ability to coordinate SBC design, harmonize activities, including messages, oversee implementation, and conduct monitoring and evaluation activities across and with 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 with the country's National Malaria SBC Strategy, and facilitate planning across various technical areas and partners. PMI further supports sub-national SBC technical working groups which play a critical role in translating national-level guidance and SBC activities to the district or provincial level for localized application.

- **Training and Development:** A critical component of the successful design, implementation, and monitoring and evaluation of SBC programs is ensuring there is sufficient trained and experienced staff to support such activities. For that reason, PMI supports the participation of NMP and Ministry of Health staff at the national and subnational level in training and development activities. A number of training options exist, including local and virtual options, and can be found in the appendix of this chapter or by contacting the PMI SBC Team.

- **Technical Assistance:** PMI also supports targeted technical assistance (e.g., strategy development, training, and mentoring) to NMPs, Ministries of Health, other relevant ministries, local civil society organizations, and implementing partners that contribute to SBC activities. Technical assistance is typically focused on planning, development, and monitoring and evaluation of SBC activities, including the selection of appropriate monitoring and evaluation indicators and review of existing data to inform SBC strategies and interventions.

Development of national malaria SBC strategy

PMI supports the development or revision of a National Malaria SBC Strategy aligned with a country's broader National Malaria Control Strategy. Such strategies are critically important as they guide the NMP, 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 NMP 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,[211] and routinely used to guide implementation of malaria SBC activities. Several resources are available to assist countries in developing their National Malaria SBC Strategy:

[211] https://endmalaria.org/sites/default/files/RBMSBCCFramework2018-2030English.pdf

- RBM SBC Working Group Template for National SBC Strategy Development[212] - 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[213] - 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[214] - 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 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 PMI country teams have questions about SBC strategy development or revision, please contact the PMI SBC Team and we can provide additional resources and guidance, as needed.

Invest Locally

Where technical capacity exists, in alignment with USAID and PMI localization efforts, PMI country teams are encouraged to invest in and partner with local entities to design, implement, monitor and evaluate SBC programs. Investing in and partnering with local partners, including locally-managed SBC organizations, community-based organizations, faith-based organizations, civil society organizations, and local research institutions, ensures SBC programs are designed and implemented by entities closest to people affected by malaria.. Where technical capacity does not exist, PMI encourages country teams to invest in and partner with local entities to strengthen their capacity to design, implement, and monitor and evaluate SBC programs. For more information on USAID and PMI's localization efforts, please refer to the Localization section of the PMI Technical Guidance.

Even when there is not a direct financial relationship between PMI and local partners, PMI-supported SBC efforts should be designed, implemented, and monitored and evaluated in partnership with NMP and MOH colleagues, sub-national MOH officials, community-based organizations, faith-based organizations, civil society organizations, and local research institutions. These stakeholders should be actively engaged in all phases of SBC design, implementation, and monitoring and evaluation to achieve

[212] https://endmalaria.org/sites/default/files/National-Malaria-SBC-Strategy-Template-2020-EN.doc
[213] https://endmalaria.org/sites/default/files/National-Malaria-SBC-Strategy-Guidance-2020-EN_0.pdf
[214] https://drive.google.com/drive/folders/1paJiNjmiHdVtfl25BZSCfpk1HV61ygcL

key results and to support activity transition to local partners over time. PMI should implement SBC approaches that build on existing systems, including national and sub-national community structures, and evidence. PMI should also support stakeholder coordination, including strengthening systems that encourage stakeholder coordination (e.g., regular coordination meetings, participation in SBC TWGs).

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. These factors include social (gender norms, social support, etc.), internal (attitudes, self-efficacy, etc.), and environmental factors (economic barriers, accessibility of services, etc.). The resulting interventions designed to address the identified factors can be communication-based (e.g., mass media, interpersonal communication) or non-communication-based (e.g., behavioral economics, human-centered design).

To ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, PMI country teams must make decisions about the desired focus of SBC efforts. To make such decisions, PMI country teams, with support from the PMI SBC Team and in collaboration with appropriate working groups in country, should regularly assess what is known about key malaria behaviors (such as the ratio of ITN use given access) as well as 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, PMI country teams can make strategic decisions about the appropriate focus of malaria SBC activities. Just as sub-national tailoring of malaria control interventions is encouraged based on available trend data (e.g., MIS, DHS, DHIS2 data), decisions about the focus of SBC activities should be tailored using data and, therefore, may vary by geography (e.g., specific districts, zones, or provinces) and target audiences (e.g., health care providers, adolescent mothers, male heads of households, etc.). As a reminder, all PMI-supported SBC activities should support the National Malaria SBC Strategy and National Malaria Strategic Plan.[215] 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, PMI country teams should work with implementing partners and other stakeholders to ensure all of these conditions

[215] 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.

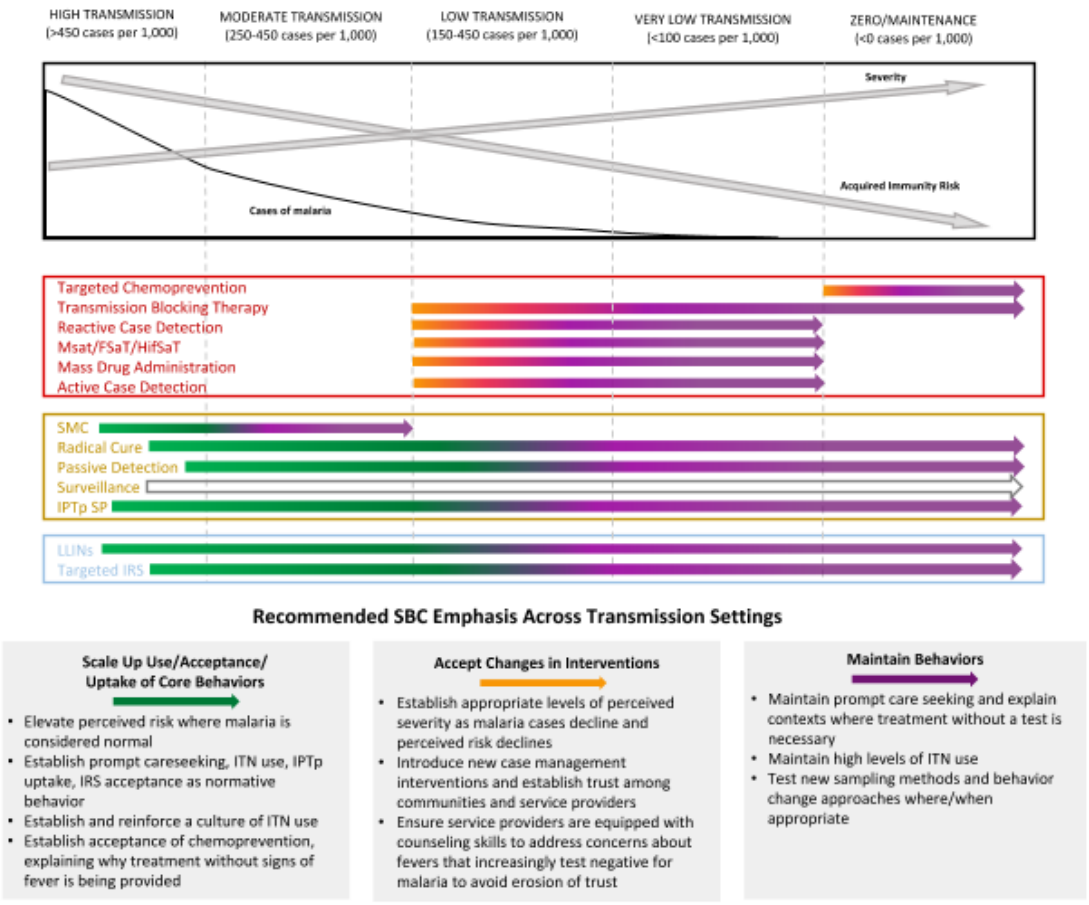
are met, requiring investment and coordination with supply chain (to ensure commodity availability), service delivery (to ensure quality of care) and SBC (to foster trust in health services available). Data sources for such an exercise can be quite varied and are outlined in more detail in the section on monitoring and evaluation.

Using available data, PMI recommends that country teams identify approximately three priority behaviors for which an SBC intervention is needed. . The exact number of priority behaviors will depend on available data and country context, however, the goal is to focus PMI's SBC investments on a few priority behaviors rather than spreading PMI's SBC investments thinly across numerous behaviors. When deciding which behaviors to prioritize, PMI country teams should carefully consider the gains that are likely to be achieved through an SBC intervention. For instance, when reviewing the internal, social, and environmental factors influencing the uptake of a specific behavior, it may become clear that the most important factor influencing the behavior is related to access and a behaviorally focused intervention would be unable to successfully address that factor. Using a simple example, an SBC activity to increase patient demand for IPTp will have limited success if stockouts of sulfadoxine-pyrimethamine (SP) are widespread. Conversely, a situation in which SP is available at ANC clinics, but where there is a common belief among ANC providers that IPTp is ineffective, would indeed call for a well-designed SBC activity targeted to service providers. Similarly, this prioritization effort could reveal that uptake of certain desired behaviors is already quite high in a given country or region. In such an instance, especially if uptake of other behaviors is low, it might not make sense to focus PMI SBC resources on trying to achieve small gains for a behavior that is otherwise widely adopted.

PMI 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.[216]

[216] http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf

Figure 7. Malaria Transmission Intensity and SBC Focus



Recommended SBC Emphasis Across Transmission Settings

Scale Up Use/Acceptance/ Uptake of Core Behaviors

- Elevate perceived risk where malaria is considered normal
- Establish prompt careseeking, ITN use, IPTp uptake, IRS acceptance as normative behavior
- Establish and reinforce a culture of ITN use
- Establish acceptance of chemoprevention, explaining why treatment without signs of fever is being provided

Accept Changes in Interventions

- Establish appropriate levels of perceived severity as malaria cases decline and perceived risk declines
- Introduce new case management interventions and establish trust among communities and service providers
- Ensure service providers are equipped with counseling skills to address concerns about fevers that increasingly test negative for malaria to avoid erosion of trust

Maintain Behaviors

- Maintain prompt care seeking and explain contexts where treatment without a test is necessary
- Maintain high levels of ITN use
- Test new sampling methods and behavior change approaches where/when appropriate

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 people affected by malaria or health workers (both facility-based and community-based). 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, as there are additional behavioral outcomes that may be of interest in specific contexts.

Table 6: Behavioral Outcomes Associated with PMI-Supported Interventions

	Primary Behavioral Outcomes	Secondary Behavioral Outcomes	Behavioral Outcomes Relevant for Specific Contexts[217, 218]
People Affected by Malaria	• Use an ITN correctly and consistently every night[219] • Attend ANC early and frequently • Accept IPTp • Seek quality care for fever within the same day or next day of fever onset[220] [221]	• Acquire ITNs for all sleeping spaces[222] • Properly care for ITNs[223]	Where relevant, • Accept application of IRS[224] • Accept and adhere to SMC • Accept and adhere to PMC • Accept and adhere to malaria vaccine schedule
Healthcare Workers (facility-based and community-based)	• Adhere to national guidelines[225] for case management and MIP	• Conduct interpersonal communication and counseling with clients affected by malaria	

[217] Please see the "special considerations" section of the SBC section of the PMI Technical Guidance for additional information.

[218] For contexts at risk of An. stephensi or areas where An. stephensi has been identified, the XX guidance includes priority behavioral objectives and SBC recommendations for An. stephensi control. There are also additional details available below in the "Special Considerations" section.

[219] Including during dry and rainy seasons, when indoors and outdoors, in both high and low transmission settings, and regardless of shape, color, or other characteristics.

[220] Timing depends on the context and should be determined by the national malaria case management guidelines. In some countries the guidelines suggest that care should be sought within 24 hours of fever onset and in some countries the guidelines suggest that care should be sought within 48 hours of fever onset.

[221] Includes facility-based healthcare workers and community-based healthcare workers where community-based malaria case management services are available

[222] Includes registering for a mass campaign, attending ANC or EPI, requesting from a CHW, or purchasing from a private sector outlet.

[223] Includes tieing up the ITN when not in use, handling the ITN gently, keeping the ITN away from children and pests, and washing the ITN in a basin with soap.

[224] Includes removing household belongings and avoiding post-spray wall modification.

[225] Includes vector control guidelines, case management guidelines, malaria in pregnancy guidelines, SMC guidelines, PMC guidelines, malaria vaccine guidelines, etc.

Once specific behaviors of focus, geographic areas of focus, and target populations are identified, PMI 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,[226] PMI identified six essential components of malaria SBC activities:

1. Formative assessments on factors that influence malaria-related behaviors;
2. A theory-informed, strategic conceptual model;
3. Audience profiles and segmentation;
4. Tailored interventions that utilize a mix of SBC approaches (communication and non-communication focused);
5. Co-design, pre-testing, and iteration; and
6. Well-timed, programmatically useful monitoring and evaluation.

These components should be integrated throughout all PMI-supported SBC interventions. PMI 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.

1. Formative assessments on factors that influence malaria-related behaviors

Human behavior is shaped by the interplay between the thought processes of individual actors, and the situations or environment in which they are making decisions. By understanding this relationship, we can begin to design SBC interventions that better meet people's needs, for the greatest possible impact.

Designing SBC activities requires a thorough understanding of not only the target behaviors and audiences, but also 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 context-specific factors that prevent or support malaria-related behaviors. Formative assessments should be used to inform decisions about the most strategic focus for PMI's SBC activities in a given country.

[226] http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf

Formative assessments should involve a review of existing country-level quantitative and qualitative data on human behavior and malaria epidemiology and/or the generation of new data on desired malaria behaviors. Data sources might include information collected from national household surveys, like the Malaria Behavior Survey (MBS), Demographic and Health Survey (DHS), the Malaria Indicator Survey (MIS), and the Multiple Indicator Cluster Survey (MICS), as well as other relevant data sources, such as health facility surveys; knowledge, attitudes, and practices (KAP) studies; ethnographic research; and health information systems. These formative assessment tools are purpose-built. For example, the DHS, MIS, and MICS surveys and health information systems provide data on behavioral outcomes and demographic factors and are best used for identifying priority behaviors, geographic focus areas, and target audiences. The MBS and KAP surveys, for example, provide data on--and confirmation of--demographic factors and psychosocial factors that influence priority malaria-related behaviors. Qualitative formative assessments, such as ethnographic research, provide data on emerging cultural and psychosocial factors that may influence priority malaria-related behaviors. Taken alone, no formative assessment tool provides a full picture, meaning multiple data sources are required to appropriately target and design SBC activities. Detailed information on data sources that can be used to inform SBC programming and described in more detail in the Monitoring and Evaluation section of this chapter.

2. *Development of a theory-informed, strategic conceptual model*

High-quality SBC activities must be based on a logical framework that identifies:

- Target behavior;
- Target audience;
- Factors preventing or supporting the behavior in the target population (why people do *or* do not engage in the behavior);
- Behavioral and intermediate[227] 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.[228] It is important to remember,

[227] The term "communication objective" was previously used, however, given the shift from SBCC to SBC and emphasis on non-communication-based approaches to behavior change, the term "intermediate objective" is now used.

[228] https://obssr.od.nih.gov/sites/obssr/files/Social-and-Behavioral-Theories.pdf

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[229] provides guidance on the development of such a model.

3. *Audience profiling and segmentation*

Audience analysis and segmentation is a critical component of any successful SBC intervention. Audience segmentation involves identifying subgroups within a larger target population and designing SBC activities 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 SBC activities. 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 Strategic Focus Area 1[230] 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 malaria control 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.[231]

Following audience analysis, audience segmentation, which involves dividing a larger audience into smaller groups with similar characteristics, can begin. For example, a target audience of health workers may need to be segmented by years of experience (junior vs. senior) or type of practitioner (doctor vs. nurse or outpatient provider vs. ANC provider). To ensure proper segmentation, clear criteria will need to be developed. These criteria should be based around traits that make groups significantly different from one another, including demographic and psychosocial factors, and which are likely to require

[229] www.thecompassforsbc.org/how-to-guides/how-develop-logic-model-0
[230] https://d1u4sg1s9ptc4z.cloudfront.net/uploads/2021/10/10.04Final_USAID_PMI_Report_50851.pdf
[231] https://www.thecompassforsbc.org/how-to-guides/how-do-audience-analysis

different SBC interventions. Detailed information on audience segmentation can be found on Health Compass' How To Do Audience Segmentation.[232]

4. Tailored interventions that utilize a mix of approaches

There are a variety of approaches that can be used to encourage behavior change among target audiences. Please refer to the Malaria SBC Evidence Database for additional information on effective evidence-based interventions. Knowledge of the local context and data from formative assessments should be used to determine the best SBC activity for the context, which may or may not be a communication-based intervention. While the majority of PMI-supported SBC activities will likely continue to be communication-based interventions, PMI encourages, where relevant, the use of non-communication-based interventions such as behavioral economics (BE) and human centered design (HCD), among others. Regardless of whether PMI-supported SBC activities utilize a communication-based intervention or a non-communication-based intervention, all PMI-supported SBC activities should (1) focus on a specific behavior, (2) be targeted to a specific audience, and (3) have a clear link to the factors (i.e., internal, social, and environmental) that need to be addressed in order for a member of the target audience to practice the priority behavior.

Communication-Based Approaches

Communication-based approaches to behavior change include mass media, interpersonal communication (IPC), community mobilization, and information and communication technology (ICT). The comprehensive evidence review conducted by Breakthrough Action recommends a multi-faceted, multi-media 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.[233]

Within that framework, PMI has historically encouraged an approximately 70 percent/30 percent split between interpersonal communication and mass media activities. This reflects contributions from other donors – primarily the Global Fund – that have historically focused their support on mass media and PMI's investments have complemented that work. It is important to note, however, that the cost per person reached with IPC is considerably higher than with mass media and thus requires careful consideration of where and how to target. The table below summarizes key considerations related to 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

[232] https://www.thecompassforsbc.org/how-to-guides/how-do-audience-segmentation

[233] http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf

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[234] and by reviewing the Malaria SBC Evidence Database.[235]

Table 7 - Communication Channels

Approach	Description	Channels
Mass Media	• One-way communication • Best for messages intended for large audiences, such as for raising awareness about goods, services, and events • Useful for reinforcing interpersonal communication, community-based, and ICT activities • Can help promote supportive social norms • 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) • Print media (e.g.,magazines, newspapers, pamphlets, and posters) • Outdoor media (e.g., billboards)
Interpersonal Communication	• Face-to-face interaction • Effective at converting knowledge to action and targeting behaviors that are more problematic or engrained that require more sensitive communication • Facilitates and encourages appropriate action, especially among marginalized populations, and helps people to discuss beliefs and feelings about their ability to take appropriate action • Useful for targeting behaviors for which multiple family members are a part of the decision making process • Reinforces mass media, community-based, and ICT activities	• Community health workers • Home visits • Counseling • School demonstrations • Peer education • Hotlines • 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	• Community health workers • Community dialogue • Community drama
Information and Communication	• Use a variety of electronic digital communication and information technology, such as web-based	• Mobile phone apps • SMS

[234] https://www.thecompassforsbc.org/how-to-guides/how-develop-channel-mix-plan

[235] https://behaviorchangeimpact.org/malaria-landing-page/

Technology	and mobile technologies and software applications, that enable users to engage in dialogue and share information • Electronic digital communication and information technology that is intended to directly improve the effectiveness and efficiency of project interventions	• Online platforms • Social media • Interactive voice response (IVR)

Engaging existing platforms and trusted messengers

In order to optimize reach, countries should engage existing platforms and trusted messengers. Leaders of community and faith organizations are a great example, plus 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 malaria-related behaviors. The Malaria SBC Toolkit for Community and Faith Leaders[236] resource and guide for community-based and faith-based organizations for incorporating malaria SBC activities into their ongoing work. Other trusted messengers with existing platforms could include, but are not limited to, teachers, community health workers, and health committees.

Non-Communication-Based Approaches: Behavioral Economics (BE)

Behavioral economics is the study of psychology as it relates to the economic decision-making processes of individuals and institutions. Drawing on psychology and economics, it explores why people sometimes make irrational decisions, and why and how their behavior does not follow the predictions of economic models. Nudges, a central concept in behavioral economics, are a way to lead people to make specific decisions. In the context of malaria SBC, a nudge would be any intervention that makes it easier or reduces barriers to a priority malaria-related behavior, such as tying up a net every night, returning to ANC on a regular schedule, or testing all suspected fever cases at a health facility. For example, in Nigeria, PMI and partners used BE to identify behavioral barriers that kept providers from following national malaria testing and treatment guidelines. Then they worked in close collaboration with partners and stakeholders to design and test interventions to address those barriers. Piloted non-communication approaches included changes to forms used by providers, the steps for validating data, and the process for client consultations. By pre-testing febrile clients for malaria before they see the provider, it gives the provider the information they need to make decisions about treatment right away and reduces the

[236] https://communityleadermalariatoolkit.org

temptation of relying on clinical intuition that may stray from national guidance. See the pilot report from a BE activity in Nigeria to learn more.[237]

Non-Communication-Based Approaches: Human Centered Design (HCD)

Human-centered design (HCD) is an approach used to improve products, services, systems from a user's point of view. It involves taking an empathetic view of the world and a deeply human perspective from beginning to end of a design challenge. HCD will often employ co-design approaches that actively and genuinely engage diverse perspectives in the design process, to ensure that the result meets their needs.

5. Co-Design, Pre-testing, and Iteration

Ideally, whether communication-based or non-communication-based, SBC interventions should be co-designed with members of the target audience, pre-tested on a small-scale before at-scale implementation, and adapted using data from co-design, pre-testing, or monitoring (i.e., iteration).

Co-design with members of the target audience ensures the SBC intervention will be culturally-relevant and context-specific as well as resonate with members of the target audience, increasing the likelihood that the SBC activity will contribute to improved behavioral outcomes. Often a prototype is developed during the co-design process. A prototype is a low-fidelity model of a potential SBC activity, material, or message. Prototypes are developed during co-design with members of the target audience. Prototypes are used to expose members of the target audience to simulated solutions within their environment (the home, the clinic, or the community). Feedback is collected from members of the target audience and used to refine the prototype before pre-testing. The purpose is not to rigorously measure performance of the prototype SBC activity but to determine elements of the prototype SBC activity that are working well and elements that require rethinking.

Pre-testing provides an opportunity to test the proposed SBC activity at small-scale, which allows for learning and refinement before at-scale implementation. Pre-testing should assess the intervention from the perspective of intended users (desirability), in the context of organizational and technical capacities (feasibility), and financial resources required to sustain the intervention (viability). How to Conduct a Pre-Test[238] provides detailed guidance on the pre-testing process, and How to Design SBCC Messages[239]

[237] https://breakthroughactionandresearch.org/wp-content/uploads/2021/04/Applying-BE-Malaria-Case-Management-Nigeria-Pilot-Report.pdf

[238] https://www.thecompassforsbc.org/how-to-guides/how-conduct-pretest

[239] https://www.thecompassforsbc.org/how-to-guides/how-design-sbcc-messages

provides a step-by-step guide to message development for communication-based SBC interventions. Pre-testing saves money, time, and energy and increases impact.

Iteration is the process of using data--from co-design, pre-testing, or monitoring--to adapt an SBC activity. Iteration is critical and aligns with USAID's program cycle principles (Principle 2: Manage Adaptively through Continuous Learning[240]). Contexts change throughout--and sometimes because of--implementation, therefore, PMI recommends using data to adapt SBC interventions throughout implementation. Iteration can occur during the co-design process, where feedback from members of the target audience is used to refine a prototype; during pre-testing, where pre-testing data about the feasibility of an SBC activity are used to modify the activity; or during implementation, where monitoring data are used to refocus an SBC activity to increase impact. See the *Monitoring and Evaluation* section below for more information on the use of monitoring data for adaptive management of SBC interventions.

5. 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 behavioral outcomes. With this focus comes a greater emphasis on accountability and reporting of SBC activities, including the development of comprehensive monitoring and evaluation plans, the selection of appropriate indicators, and the measurement and tracking of those indicators. PMI recommends monitoring intermediate outcome indicators (i.e., indicators related to behavioral factors that influence malaria-related behavioral outcomes) as well as monitoring output indicators. Monitoring both intermediate outcome indicators and output indicators will allow for iteration and adaptive management of SBC activities, as mentioned above. A plan for monitoring and evaluating SBC activities should be developed at the time of SBC activity design. Monitoring and evaluation of SBC activities is explored in greater detail in the "Monitoring and Evaluation" section below.

SBC in Service Delivery

A growing area of focus for PMI's SBC efforts relates to health care provider behavior, service communication, and collaboration with service delivery stakeholders for malaria in pregnancy and case management services at the health facility and community levels. Utilizing an SBC lens to understand and address factors influencing provider behaviors, such as providers' sense of self efficacy, perceptions of the response efficacy of malaria diagnosis and treatment products/proven interventions (e.g., adherence to RDT results), attitudes and norms, is essential for interventions aimed at improving the quality of

[240] https://usaidlearninglab.org/sites/default/files/resource/files/dn_adaptive_management_final2021.pdf

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 clients(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 clients receive and may influence clients' 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 case management and MIP will not be possible. Challenges related to provider behavior can manifest in a number of ways, including:

- Missed opportunities to provide IPTp and ITNs during ANC visits;
- Failure to provide the correct antimalarial in an appropriately diagnosed patient (e.g.,treating uncomplicated cases with injectable treatments);
- Failure to refer a patient receiving pre-referral treatment for severe malaria to a higher-level health facility;
- Providing ACTs to clients with negative test results; and
- 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 health facility surveys. In these data collection efforts, it is essential to triangulate data sources to assess and characterize the factors influencing provider behavior in order to identify appropriate interventions. Factors related to health facility infrastructure, accepted workplace norms, patient demands, and health worker skills and capacities will all call for different types of intervention response.

Activities to address these particular provider behaviors may benefit from coordination across SBC, service delivery, and surveillance, monitoring, and evaluation partners. Formative assessments will likely

be needed to design SBC activities that effectively address the internal and social factors that influence provider behaviors and should be done in collaboration with service delivery partners who have valuable information on provider behaviors. 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[241] is a framework for understanding provider behavior that can be used when developing strategies for provider behavior change, or at any point during implementation of provider behavior change activities, to identify factors that influence behavior, develop appropriate targeted activities, and conduct monitoring and evaluation.

Another promising approach is the application of behavioral economics methodologies as described in the previous section. 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 as referenced in the PMI Nigeria example in the previous section. (Link to learn more about Breakthrough ACTION's BE work in Nigeria.)

As described in the Case Management section, 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. In such instances, these opportunities should also account for behavioral factors relevant to private sector behavior practices (e.g., reporting, prescription practices, relevance of regulatory policies, etc.). It should be recognized that appropriate SBC activities targeting behaviors of private providers may be more complex. Please contact the PMI SBC Team for assistance, as needed.

Service communication

Service communication is the use of SBC activities by healthcare providers to influence malaria-related behaviors among clients 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.[242]

[241] https://breakthroughactionandresearch.org/wp-content/uploads/2020/10/Blueprint-Applying-Behavioral-Insights

[242] http://sbccimplementationkits.org/service-communication/

As PMI intensifies efforts to strengthen community health platforms, supporting CHWs to deliver effective SBC - either during their routine case management activities with clients 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

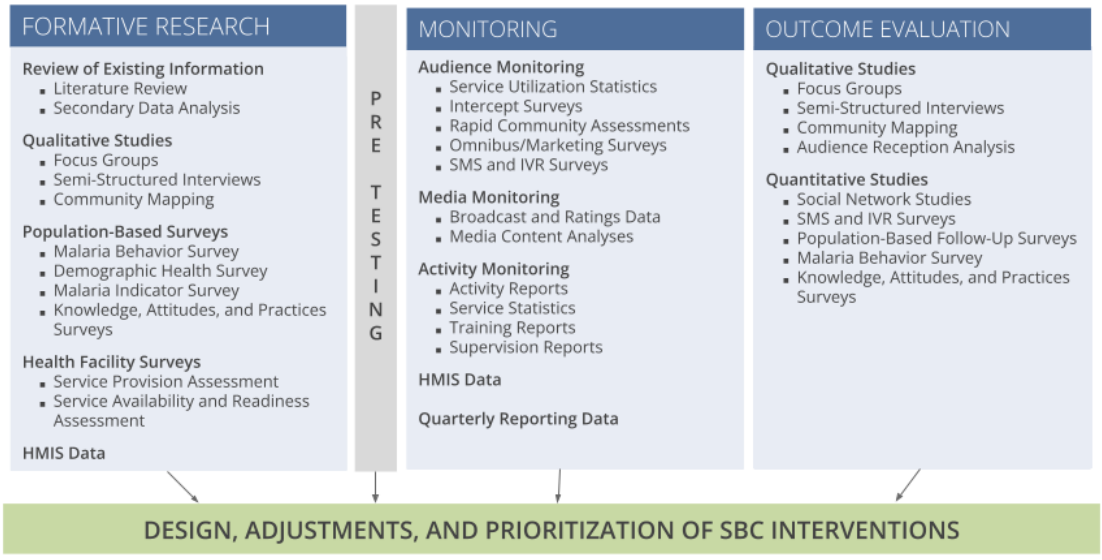
Coordination between SBC and service delivery actors is essential to align supply (service provision) and demand (client demand) efforts and can provide critical data to both sets of actors that they might not otherwise be able to access. These data can be used to target providers, including CHWs, for 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 PMI SBC 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. Where PMI is supporting service delivery efforts within the private sector, it is encouraged that SBC actors are engaged in order to address the nuances of service provision and demand.

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 monitoring and evaluation of SBC activities. This can be achieved through the development of a comprehensive and systematic monitoring and evaluation plan that draws on previously identified logic models and behavioral and intermediate objectives for the selected SBC approach. Monitoring and evaluation plans should use a practical framework (see Figure 8) to illustrate activities for formative assessments; baseline evaluation and indicator development; process and audience monitoring; and endline (outcome) evaluation.

Figure 8. Framework for SBC Monitoring and Evaluation



Partner monitoring and evaluation plans for SBC activities should include the following components:

- Behavioral objectives, intermediate objectives, and a detailed description of the SBC activities designed to address those objectives;
- Indicators for each objective, including operational definitions;
- Targets for both the desired behavioral outcomes and the associated behavioral factors;

- Timeline for data collection and analysis in relation to activity implementation (i.e., formative, baseline, midpoint, endline); and
- Information about the data sources that will be used to calculate the indicators, the reporting frequency, and responsible parties.

More details about each of these components, as well as guidance on developing a comprehensive and systematic monitoring and evaluation can be found in the RBM Partnership to End Malaria's guidance titled Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide.

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 PMI SBC Team developed a Malaria SBC Site Visit Monitoring Checklist. The checklist can be used by PMI 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 PMIcountry team's programmatic use and does not need to be shared with the PMI 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), health facility surveys, routine data sources (e.g., HMIS, OTSS), and other relevant sources. Depending on the behavior of interest and target audience, each data source may be more or less relevant.

- **Malaria Behavior Survey:** The MBS[243] 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. This tool is complementary to data collected through the MIS, DHS, and MICS as it is intended to help describe specific factors (attitudes, risk perception, self-efficacy, perception of health workers, etc.) that influence intervention uptake. To facilitate strong, data-driven, theory-informed SBC

[243] http://malariabehaviorsurvey.org/

interventions, ***PMI 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[244]. In multiple countries, PMI and Global Fund have successfully co-financed an MBS. Please contact the PMI SBC Team for more information on the timing (for baseline/formative research and interest in implementing a second iteration) and cost considerations of implementation. The timing and scope will also need to be negotiated with the NMP, in coordination with the SBC and S&I 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 NMP, in response to stagnation or lack of progress, or any other point where behavioral data are needed to guide programmatic decision making. However, PMI recommends the MBS not be conducted in the same year as an MIS, MICS, or DHS. Due to the intensive nature of these surveys, PMI recommends that an MIS/DHS/MICS and MBS not be implemented within the same year, and ideally, be conducted a minimum of eighteen months apart. Given the Surveillance & InformaticsTeam'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. ***Please discuss with the PMI SBC Team if your country team intends to plan for a second iteration of the MBS.***

- **Scope:** For countries interested in implementing a nationwide MBS, PMIrecommends 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:** PMI worked with Breakthrough ACTION to develop a questionnaire and implementation guidance tailored to low-transmission settings. The adapted questionnaire, developed in collaboration with the

[244] Cost of implementing the MBS will vary by a number of factors: sample size, scale of the survey (national or targeted geographic regions), market costs for data collection firms, transportation/fuel costs for data collection and supervision, translation needs, and country operational costs. To date, the cost of MBS implementation has ranged from about $275,000 (for limited geographic coverage) to $620,000 (in DRC with a national scope).

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 CY2021, is ready for use, and is available on the MBS website.

- **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[245] 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 a monitoring and evaluation plan for an SBC activity. For example, the DHS and MIS may not provide the subnational estimates required to measure outcomes of a specific SBC activity, especially if the activity is targeted to a limited geographic area. In addition, the DHS and MIS may not provide enough information on key 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,

[245] https://www.dhsprogram.com/publications/publication-MISQM-MIS-Questionnaires-and-Manuals.cfm

KAP studies often do not collect systematic data on the full range of ideational variables that influence the uptake of malaria-related behaviors.

- **Health Facility Surveys and Routine Data Sources:** Data from health facility surveys or routine data collection systems can provide insight into various aspects of patient-provider interactions and can be useful for designing and assessing activities targeted towards health workers. Data collection methods include patient observation, patient exit interviews, provider interviews, and register abstraction. Additional efforts are being made to improve the data collected on health care provider behaviors (e.g., development of standardized questions to assess provider behavior in health facility surveys and a rapid behavioral diagnostic tool). Existing health facility data sources, such as routine data (e.g., HMIS, OTSS data, commodity inventories, etc.), also provide insight on provider behaviors and commodity availability. It is important to note, however, that there is currently no standardized protocol for health facility-based SBC data collection. As such, quality and completeness should be considered when interpreting the data.
- **Other Sources:** Tools used for durability monitoring and end process evaluations of mass net and SMC campaigns provide key information on behaviors related to ITN use and care and SMC adherence. Activity reports from implementing partners can also be used as data sources for monitoring and evaluation of SBC activities. Other monitoring tools, such as media monitoring for radio/television/social media, mobile phone surveys, media content analysis, and rapid exit surveys, can also be useful in an SBC monitoring and evaluation plan. For example, media monitoring can be commissioned from third-party organizations to ensure broadcasts are aired as planned. Omnibus surveys, which are regularly occurring large surveys conducted for marketing purposes, are another useful tool. Omnibus surveys can be used to track exposure/recall and assess changes in targeted behavioral factors. National or regional-level samples can be obtained but sampling strategies are not as robust as DHS and MIS surveys. For more details on the advantages and limitations of all data sources mentioned, please refer to RBM Partnership to End Malaria's SBCC Indicator Reference Guide[246] and Breakthrough ACTION's SBC Monitoring Guidance.[247]

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

[246] breakthroughactionandresearch.org/wp-content/uploads/2018/03/Malaria-SBCC-Indicator-Reference-Guide-ENG-2017-Sept.pdf
[247] breakthroughactionandresearch.org/resources/social-and-behavior-change-monitoring-guidance/

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 intermediate objectives and should include indicators that measure actual behavior (i.e., behavioral objectives), as well as those that measure behavioral determinants (i.e., intermediate objectives). As appropriate, indicators for both people affected by malaria and providers should be considered. For more information on indicator development and prioritization, please refer to the RBM Partnership to End Malaria's SBCC Indicator Reference Guide, which was developed to ensure a rigorous standardized approach to SBC monitoring and evaluation efforts. The indicators included in the reference guide are not considered required reporting indicators for PMI. However, PMI partners are strongly encouraged to use the indicators to design, monitor, and evaluate SBC activities.

Process monitoring and audience monitoring

Since endline evaluations only occur periodically (often only every 2-5 years), process and audience monitoring are essential for tracking whether activities are being implemented as planned and determining if desired changes are starting to emerge in the target population (e.g., changes in knowledge, attitudes, risk, efficacy, norms). This type of monitoring can and should be done using a variety of data sources as described above. If monitoring activities indicate that desired changes are not beginning to emerge, program adjustments should be made, including adjustments to channel selection.

Endline evaluation

Endline or outcome evaluation should be conducted to assess and document changes in behavior and behavioral determinants as a result of SBC activities. It may not always be possible to attribute changes in behavior, and to an even greater extent, changes in health impact, to a specific SBC activity; however, descriptive behavioral outcome data, even in the absence of a statistically significant association, can suggest potential associations with SBC activities and be used to inform programmatic decision making. This association is strengthened even further if: (1) activities were implemented as intended, (2) the target audience was reached, and (3) the target audience demonstrated a change in targeted behavioral factors (e.g., risk perception, efficacy, attitudes, norms). The strength and confidence level of any

measured association will depend upon data collection, sampling, and analysis methods. As mentioned previously, the MBS is designed to collect systematic data on the full range of ideational variables and is intended to be used as a formative assessment tool *and* evaluation tool following the recommendation to implement approximately every five years.

Special Considerations

Malaria Vaccine

As PMI partner countries begin to introduce the malaria vaccine, PMI country teams may be asked to support malaria vaccine introduction. One way that PMI can support the introduction of the malaria vaccine is through SBC. A key takeaway from the three Malaria Vaccine Implementation Pilot (MVIP) countries was the importance of SBC to promote the adoption of the vaccine while maintaining the demand for other malaria interventions and other routine immunizations. To support the introduction of the malaria vaccine, PMI may support SBC activities to promote demand for the malaria vaccine. PMI should integrate malaria vaccine SBC activities into existing PMI-supported and EPI-supported SBC activities in areas where the malaria vaccine will be introduced. Considerations for PMI's support for malaria vaccine SBC include:

- Establish a coordination mechanism for malaria vaccine SBC that includes representatives from across the MOH, including the NMP and EPI programs.
- Development of a malaria vaccine SBC strategy integrated into both the national malaria SBC strategy and national immunization demand creation strategy.
- Simultaneously emphasizing the importance of malaria vaccine uptake as well as the uptake, maintenance, and use of proven malaria control interventions throughout malaria vaccine implementation.
- Designing and implementing data-driven SBC interventions.
- Integrating promotion of the malaria vaccine in general and in child health platforms at facility and community levels.
- Supporting providers and provider-related behaviors through provider behavior change and supporting providers to advocate for the malaria vaccine and other malaria control interventions through service communication.
- Engaging with influencers on the expanded immunization schedule including the second year of life in the childhood series.
- Monitoring and responding to emerging hesitancy, rumors, and misinformation and disinformation.

The PMI SBC Team and USG Malaria Vaccine Implementation Working Group are contributing to the development of global malaria vaccine SBC guidance which should be available in 2023.Please refer to the Vaccine Chapter for additional information.

IRS, SMC, and PMC

Acceptance and uptake of IRS, SMC, and PMC 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, SMC, and PMC. Where IRS, SMC, and PMC are implemented, in most instances, vector control or service delivery partners lead community mobilization efforts for IRS, SMC, and PMC. PMI 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, SMC, or PMC when specific issues arise or when available data suggests there are significant challenges around acceptance of IRS, SMC, or PMC.

Larval Source Management

As described in the Vector Control chapter, there is a limited set of circumstances in which larval source management interventions may be appropriate. These interventions, which involve the destruction of larval habitats via draining or filling or through the application of larvicides, are designed to be systematic and require a high degree of rigor to have an impact on community-wide malaria transmission. Such programs are best implemented by vector control experts and do not rely on individual-level action by community members. However, in some countries, as part of their approach to larval source management, NMPs 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. The exception being larval source management for *An. stephesi* (see below).

Anopheles stephensi

SBC to promote evidence-based individual, household, and community behaviors to reduce *An. stephensi* populations should play a critical role in the response to this growing threat in Africa. Once a response to *An. stephensi* has been identified, a corresponding SBC strategy should be incorporated to promote the interventions and associated factors that support the uptake and maintenance of interventions to combat invasive *An. stephensi*. Breakthrough ACTION, in collaboration with the PMI SBC and Vector Control Teams, is developing SBC guidance for *An. stephensi* in Africa that will be available in CY2023. There is a need for unique consideration for **urban areas** where SBC strategies

may need to increase malaria risk perception and target and/or be tailored to groups of people at higher risk for malaria. This may include groups such as migrant or construction workers who move between higher and low transmission areas or whose risk may be increased due to their occupation. The guidance will include SBC considerations for interventions that have not yet been widely applied for malaria control in the sub-Saharan African setting: implementing household larviciding, community larviciding, regularly finding and removing standing water, and covering water storage containers. The guidance will also include unique considerations for promoting core malaria interventions (ITNs, IRS, care-seeking for fever) in areas where *An. stephensi* has been identified or where there is risk of invasion.

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, lead to a higher proportion of cases progressing more rapidly to severe disease. In this context, SBC interventions will need to be adjusted to target different populations and behavioral factors, utilize new channels, and adjust how behavior change is measured (see Figure 1 above). Behavior maintenance will also become more important, especially with regard to ITN use. There is no single correct approach for SBC in elimination settings. However, it is critical that countries understand how behavioral determinants, like risk perception and response efficacy, are different in low-transmission settings. To assist with this, and as noted above, the SBC 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.[248]

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

[248] http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf

strengthened to ensure continued delivery of malaria interventions among communities, households, and individuals.

Specifically, approaches to malaria SBC must incorporate guidance developed by the World Health Organization (WHO) and host country governments to address public health emergencies, such as revised treatment policies, limits on public gatherings, handwashing guidelines, etc. Depending on the mechanism of transmission, public health emergencies may require the curtailment of IPC activities, including social mobilization, community engagement, community meetings, or household visits. If this occurs, malaria SBC interventions may need to be adjusted to utilize mass, mid-, digital, and social media approaches. However, if planned IPC activities are to be conducted in conjunction with life-saving malaria prevention, testing, or treatment activities (e.g., ITN mass campaign, IRS campaign, or SMC campaign), it may be appropriate to move forward with IPC at the community-level. This should only be done, however, after careful review of international and national public health emergency guidelines, discussions with relevant stakeholders, and careful consideration of the safety of those conducting and participating in community-level IPC activities. As with the COVID-19 pandemic, international organizations, such as WHO Global Malaria Programme and RBM SBC Working Group, may develop guidelines to assist countries in the implementation of malaria SBC within the limitations imposed by the public health emergency. See, for example, Malaria SBC Program Guidance in the Context of COVID-19 Pandemic.[249]

Zero Malaria Starts With Me

Zero Malaria Starts with Me (ZMSWM) is a continent-wide advocacy campaign for a malaria-free Africa co-led by the African Union Commission and the RBM Partnership to End Malaria. Implementation of ZMSWM is intended to contribute to increased political, private sector, and community commitment to and engagement in malaria control and elimination efforts, and in recent years, several PMI countries have endorsed the platform as a core component of their National Malaria SBC Strategy. It is critical, however, that participation in ZMSWM is accompanied by continued investments in the design and implementation of evidence-based, theory-driven SBC activities at the community, district, regional, and national levels given that malaria control and elimination requires individual behavior change in addition to broader advocacy efforts. Indeed, **ZMSWM and SBC are complementary approaches**—and they should be implemented as such. **ZMSWM should not replace ongoing community-level, district-level, regional-level, and national-level SBC activities,** and ongoing implementation of SBC activities should not preclude countries from adopting ZMSWM. PMI funding should be used to continue to support the design and implementation of evidence-based, theory-driven SBC activities aimed at increasing the practice of specific behaviors, not advocacy campaigns. Through the PMI's active engagement with the RBM SBC Working Group, and in consultation with the RBM Strategic

[249] https://endmalaria.org/sites/default/files/Malaria-SBC-Guidance-in-the-Context-of-COVID-19

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*** operational research and are an expected and desired aspect of SBC programming. However, as PMI country teams confront SBC-related operational research questions, such questions should be discussed with relevant stakeholders for consideration of how to prioritize and address those questions. PMI 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 operational research activities, protocols should be developed in accordance with the process outlined in the Operational Research and Program Evaluation Chapter.

Peace Corps

Guidance for collaboration with the Peace Corps is available in the Health Systems Strengthening chapter. However, as it relates to SBC activities, Peace Corps and Peace Corps Volunteers are a potentially great resource. It is recommended that PMI country teams ensure that Peace Corps' malaria SBC activities are aligned with NMP SBC efforts, complement PMI-supported SBC activities, are evidence-based and theory-informed, and contribute to the behavioral and intermediate objectives outlined in the National Malaria SBC Strategy. Whenever possible, Peace Corps and Peace Corps Volunteers should participate in existing or ongoing SBC activities rather than designing and implementing parallel SBC activities.

Management and Budget

PMI support for SBC activities should be commensurate with the overall PMI budget, the magnitude of the behavioral challenges, and the SBC investment by other stakeholders. As articulated in PMI Policy, and as with all PMI investments, PMI country teams are expected to actively manage and monitor SBC investments:

- In the event that the COR/AOR of a bilateral SBC mechanism or bilateral mechanism with a SBC component is not a member of the PMI country team, a member of the PMI country team should serve as an Activity Manager for the malaria SBC activities.

- For countries that buy into a central SBC mechanism, the PMI country team is expected to select a member of the country team to serve as a Mission-based Activity Manager for the malaria SBC activities regardless of whether the buy-in is across numerous health areas. The Mission-based Activity Manager will work with the headquarters-based Activity Manager to manage the malaria SBC activities.

- All PMI-supported implementing partners and projects are expected to coordinate and collaborate with PMI-supported SBC implementing partners and projects at the national and subnational levels. To ensure this occurs, PMI country teams are expected to help create strong linkages between SBC projects and other projects within the PMI portfolio. For example, SBC projects working to increase careseeking should be linked with service delivery projects working to improve the quality of malaria case management. These linkages are critical given the cross-cutting and supportive nature of SBC.

- PMI country teams are also expected to coordinate SBC activities with the Global Fund Principal Recipient and other implementing partners and donors to ensure the implementation of complementary and reinforcing SBC activities.

The SBC Team is committed to supporting PMI country teams with design, implementation, monitoring, and evaluation of SBC projects and activities. Members of the SBC Team can provide virtual, as well as in person support. Virtually, SBC 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 Team is responsible for supporting specific countries on issues related to SBC.[250] Similarly, to facilitate communication with the PMI SBC Team, PMI country teams are asked to identify a single SBC point of contact (POC). The SBC POC will be the primary contact for the SBC Team regarding SBC. The SBC Teams will send periodic updates to SBC POCs and host periodic coordination calls with SBC POCs. The SBC Team also encourages SBC POCs to reach out to their

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

SBC backstop to request assistance related to SBC activities and to share SBC work plans and deliverables.

Table 8. 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.
	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.
	Guidelines for Costing of Social and Behavior Change Health Interventions	Framework for estimating the cost of interventions for SBC to allow assessment of cost-effectiveness and benefit-cost ratios programming.
	Programmatic Research Brief: Are Integrated Social and Behavior Change Interventions Cost-effective?	Overview of the steps for examining the cost-effectiveness of integrated SBC programs that can be used for future cost-effectiveness analyses.
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 program evaluation 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.
Specific Technical Areas	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 Insecticide-Treated Nets	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.
	Monitoring And Evaluation For SBCC - Malaria Case Management	How-to guide on monitoring and evaluating SBC components of malaria case management 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 malaria in pregnancy, especially those interventions that target healthcare worker.
	Malaria SBC Toolkit for Community and Faith Leaders	Guide for faith and community organizations aimed at capacity strengthening 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 monitoring and evaluation.
	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 & INFORMATICS

Key Messages

***New*:** In early 2022 the PMI Surveillance, Monitoring and Evaluation (SM&E) and Data Integration (DI) teams combined to form the PMI Surveillance and Informatics (S&I) team. The S&I team continues to support core components of SM&E which includes household surveys, facility surveys, improving routine health information systems, and surveillance activities. In addition to these activities, the S&I team also supports data visualization, Malaria Data Integration and Visualization Platform (M-DIVE) reporting, and continued malaria data integration, analysis, modeling, interpretation of trends, digital health activities, and discussions on national data repositories.

Health management information systems (HMIS) are a key investment area for PMI. Although a single partner may not be responsible for everything that needs to be done to strengthen routine health information systems, a checklist of PMI-recommended activities can be used to identify gaps across partners and prioritize support for activities (Box 1). To better document PMI support for HMIS strengthening plans, more information should be provided on the NMP 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 (Surveillance, Monitoring and Evaluation Reference Group) 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; these activities should collaborate with relevant partners as the Global Fund will also make funding available for these assessments through their grants.

Strengthening community-based information systems

As community health worker 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 Table 2 to track investments in this element of PMI's strategic focus on strengthening community health systems.

Subnational tailoring exercises

PMI participation in stratification and sub-national tailoring exercises is highly encouraged to help inform the data inputs, modeling assumptions, and country context issues to ensure an aligned process for effective decision-making. If you have questions about stratification, how to be engaged and what to look for as your country is beginning the process, please reach out to the S&I team. Please read more details in the stratification section of this guidance.

Malaria Data Repositories

There is a global call for the development of country owned malaria data repositories to aid NMPs in monitoring their programs. The development of a data repository requires financial commitment over a number of years along with continued input from all stakeholders and a dedicated team to work closely with all data and systems owners. As country repositories are being built and HMIS systems continue to be strengthened, country teams and partners can utilize the M-DIVE platform to access data, test new tools, and develop ideas for their repositories. If there are questions about how to use M-DIVE, please contact the PMI S&I Team.

Nationally Representative Surveys: Recommended Frequency and Biomarkers

Household surveys will continue to be a key surveillance, monitoring, and evaluation (SM&E) activity:

- In moderate- to high-prevalence areas, household surveys are recommended every 2–3 years
- PMI recommends that in countries where national parasite prevalence in children under 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin testing through national surveys should be discontinued.
- In countries with national parasite prevalence in children under 5 years of age at or below 3% at the national level, while it is recommended to discontinue the collection of parasite burden by microscopy or RDTs, household surveys are still recommended every 3–5 years to continue to assess intervention coverage.
- In lower burden countries (<5% 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 S&I POC to discuss this option.
- **The DHS-8 project will end in September 2023. If your country is planning a household survey (DHS or MIS) in 2024 or 2025 please contact Misun Choi as soon as possible to discuss funding options.**

Health facility surveys (HFS) such as the Service Provision Assessment (SPA) or Service Availability and Readiness Assessment (SARA) **are primarily used for program monitoring and help monitor readiness of a health facility to provide quality care and assess quality of care**. As a general rule, these HFS should not be repeated more than every 3 years to allow time for interventions and/or policy changes to produce measurable change. Note that there are many other facility survey tools that are used to conduct targeted investigations, operations research, assess data quality and check

the availability of commodities (e.g., EUV). For more information, please refer to the HFS section of this guidance document.

Elimination:
The PMI Strategy 2021–2026 again includes an elimination-focused objective: to accelerate towards elimination in 10 countries and eliminate in ≥1 country. Elimination as a subnational or national goal requires that malaria control and elimination activities must increasingly be tailored and geographically localized based on malaria risk stratification (sub-national tailoring) to address the specific needs of areas with differing epidemiologic profiles. This can only be accomplished if countries strengthen the capacity to collect, analyze, and interpret quality health management information system (HMIS)/malaria surveillance information. Please refer to the Elimination technical guidance chapter for additional information and resources.

*For guidance on entomological monitoring, ITN durability monitoring, 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.*

Please note that guidance for the Field Epidemiology Training Program is available in the Health Systems Strengthening Section.

Introduction

PMI's strategy for 2021–2026 focuses on a world free from malaria. The three strategy objectives continue to be focused on mortality reduction, morbidity reduction, and moving countries toward elimination.

The goal of PMI's updated strategy for 2021–2026 involves working with NMPs 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 ten PMI partner countries toward national or subnational 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

Surveillance, monitoring and evaluation are core components of PMI S&I activities. PMI is a member of the RBM Partnership and, as such, SM&E activities should, whenever possible, be carried out in coordination with other major partners and donor agencies, including the Global Fund, World Bank, WHO, UNICEF, etc. Surveillance, monitoring, and evaluation activities should also be in line with the principle of "The Three Ones" – one national malaria coordinating body, one national malaria control/elimination strategy, and one national malaria SM&E plan – by supporting national SM&E strategies and encouraging NMP leadership in SM&E. PMI should seek ways to support and strengthen MOH and NMP capacity in SM&E by providing appropriate technical and material resources to build human and system capacity at the various operational levels throughout the national health system. Collaboration with other USG partners such as PEPFAR, USAID MCH programs etc., should be sought.

Cost-effective, sustainable solutions

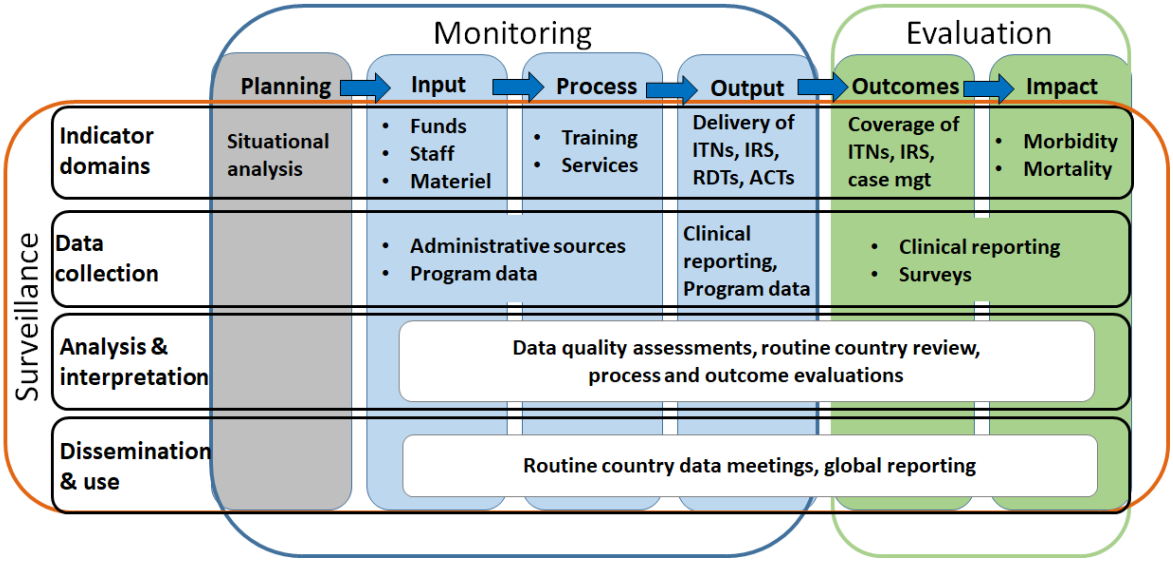
The PMI Headquarters S&I Team is cognizant that funding for malaria and SM&E activities is finite and therefore strives to ensure that PMI-proposed SM&E activities are the "best buy" for countries and donors. Surveillance, monitoring, and evaluation activities should provide cost-effective long-term solutions, and promote approaches and systems that are or can become sustainable with country resources. Although efficiencies in acquiring SM&E data and information for malaria may tempt the support of stand-alone malaria SM&E activities, every effort should be made to ensure that PMI-supported activities are integrated into larger public health needs, leverage other investments (e.g., PEPFAR, MCH), and build on local approaches and capacity.

SM&E Framework

PMI follows the SM&E framework shown in Figure 9 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 9: 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, subnational estimates are also required and attention to measuring transmission reductions should be considered. 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/MICS 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/MICS 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 may be a substantial overall decrease in child mortality accompanied by a proportional shift in malaria morbidity and mortality extending beyond children under five years of age to older age groups (as malaria deaths are especially prevented among the youngest children. 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 NMPs through routine health information systems (RHIS) are a primary data source for hospital-based deaths from malaria. It is important to emphasize that hospital-based deaths grossly underestimate the actual number of malaria deaths because many deaths occur at home, or at facilities not reporting to routine systems. However, trends in mortality can be tracked through longitudinal facility-based data collection systems and, when controlling for factors such as increasing completeness of reporting and increases in health facility use, suggest changes in malaria mortality and case-fatality rates over time.

Objective 2 - Reduce 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 national malaria control programs and donors in such settings.

To date, weaknesses in most routine health information systems have limited their use in following morbidity trends. The expansion of the District Health Information System 2 (DHIS-2) platform in many countries has contributed to more complete, accurate, timely, and accessible routine health data. As these systems continue to improve, routine health information will be critical to monitoring changing epidemiology, targeting resources and interventions, and measuring impact. Therefore, PMI encourages more investment in disease surveillance strengthening through routine health information systems; activities that include building the system and capacities to manage the system and improved data quality, use and visualization for decision making.

In most PMI partner countries, Health Management Information System (HMIS) 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 HMIS 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 HMIS data systems is ensuring that malaria services provided by community health workers are captured and incorporated (ideally in a disaggregated format by sex and age) as part of the regular HMIS system. 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 WHO Surveillance Assessment Toolkit is available on the WHO website.

Additional guidance on these routine health information systems and population-based surveys is in the **Guidance on S&I Approaches and Tools** section below.

Objective 3 - Assist at least ten PMI partner countries to achieve national or sub-national elimination

PMI uses test positivity rate (TPR below 5%) and/or annual parasite incidence (API below 10 per 1,000 population) to monitor both subnational and national elimination areas. Countries or sub-national areas approaching elimination must have a highly functioning routine health information system that includes reporting of cases diagnosed from all sectors, including public, private, non-governmental organizations, military, etc. Use of digital tools may facilitate collecting and reporting data in this way (see Digital Community Health section for more information).

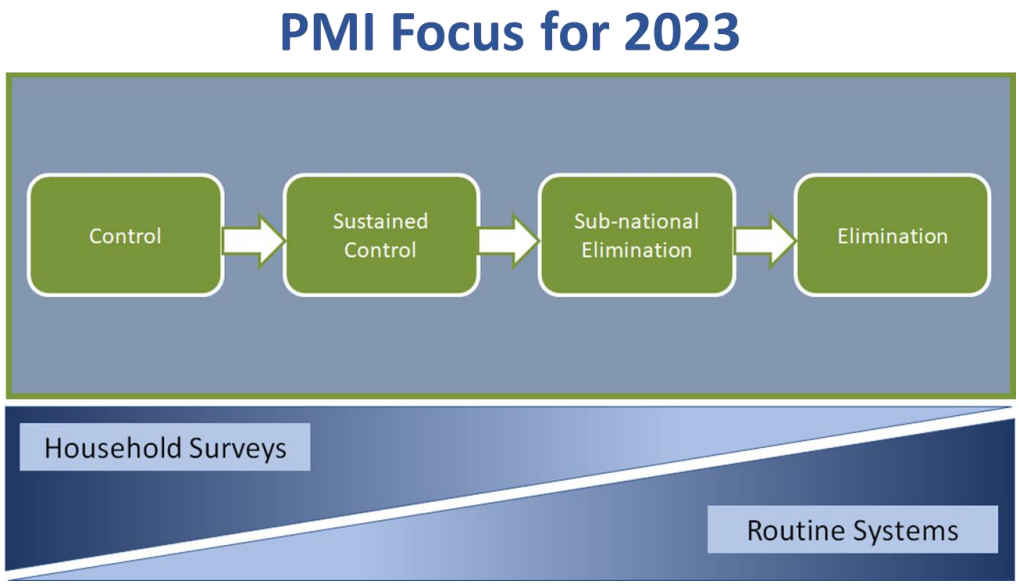
Elimination activities related to case investigation and response such as 1-3-7 (e.g., report, investigate, respond) surveillance and reactive case detection strategies, etc. should be noted and these activities should be included in the MOP budget table under SM&E for elimination. A more detailed discussion on SM&E and surveillance system considerations and requirements in elimination settings (both national and subnational) as well as a list of recommended indicators, can be found in the **Elimination** chapter.

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 10**). 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 10: Changing SM&E in the Context of Progressive Phases from Malaria Control to Elimination



Guidance on S&I Approaches and Tools

Malaria disease surveillance

Malaria disease surveillance plays an important role in the monitoring and evaluation of malaria control programs. In the context of PMI, disease surveillance is the continuous systematic collection, processing,

analysis, presentation, interpretation, and dissemination of malaria data from service delivery points to those responsible for malaria control to use for timely decision-making as well as feedback to the original service delivery points. Malaria surveillance data can be used to identify areas in need of more intensive interventions, targeted implementation research, and to measure the impact of interventions. When accurately recorded and reported, these data are important for monitoring changes in malaria over time. PMI recognizes that the country context – health system capacity, malaria epidemiology, implementing partner experience, among others – will determine how to best implement malaria surveillance.

For reference, the link to the WHO guidance on malaria surveillance for control areas is https://apps.who.int/iris/bitstream/handle/10665/272284/9789241565578-eng.pdf). For countries moving towards elimination, please contact the PMI Headquarters S&I Team and Elimination Technical Team for guidance. The 2017 WHO Framework for Malaria Elimination also has useful information on SM&E activities in elimination settings (https://apps.who.int/iris/bitstream/handle/10665/254761/9789241511988-eng.pdf). Additionally, unit 5 in the 2022 WHO Malaria Elimination Course https://openwho.org/courses/malaria-elimination is dedicated to surveillance considerations in low burden settings.

Routine health information systems (RHIS)

RHIS will be important for measuring the impact of PMI interventions going forward. The RHIS is based on clinical data passively collected from health facilities, and in some cases includes data collected from the community. The type of RHIS used by national programs will vary from country to country. The most common system used in PMI 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/year). Moderate/high malaria burden areas maintain levels of immunity that make

epidemics much less likely. In moderate/high burden settings, countries should not use limited resources to investigate **"outbreaks"** as these are most likely "upsurges" in malaria cases that do not require an outbreak response. In settings that are low and 'seeking-elimination', these "upsurges" will often represent 'foci of ongoing transmission' and should be managed as 'foci' (per the elimination framework) rather than as "outbreaks". Case counts (or incidence) along with reporting quality should be monitored on an on-going basis to assess trends and inform program activities. An upsurge in cases should be assessed to determine whether or not it is a data quality issue and whether adjustments to malaria control interventions may be necessary (e.g., ensuring that supply of ACTs/RDTs are able to meet the increased demand or distributing additional ITNs if coverage is suboptimal). 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.[251] While issues of completeness and accuracy remain, this should not keep countries from using this information 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 trends and combine financial, climate, and epidemiologic data for improved understanding and tracking of investments (See **M-DIVE** section). As country HMIS systems are improved and repositories are built, NMPs are encouraged to utilize M-DIVE to organize data and test out new visualizations and tools to generate ideas for country owned systems and repositories.

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

[251] 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.

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. In many PMI country teams, the data specialist position has been added to further support PMI team evaluation of RHIS data quality, analyses of available data sources and use of data for decision-making.

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 Headquarters S&I Team.

Parallel malaria reporting structure: This is an alternate reporting route for RHIS malaria data to ensure the data are received by the NMP. In some countries, it has been difficult for the NMP to access routine data from the HMIS or IDSR in a timely manner (or at all). In such circumstances, this should be discussed with the MOH leadership to determine if there is any way to provide access to the NMP. If it has been determined that access is not possible, PMI may support the NMP to develop a reporting "work-around" where districts or facilities report routinely collected malaria data directly to the NMP in addition to the formal reporting mechanism for the RHIS. As above, PMI may provide this support as a temporary solution to NMP data access issues, but again, only as part of a broader strategy to strengthen RHIS. The decision to support or develop a parallel reporting structure should be clearly justified and made in consultation with the PMI Headquarters S&I 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 is 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 case management interventions. As targeted districts and facilities reach the end of their phased period, additional districts and facilities may be selected. The long-term goal of this targeted approach should be to strengthen RHIS and 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, NMP, and all partners.

Activities supported

PMI support for RHIS activities may include those in Table 9. 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 9: 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 quarterly report requests.	☐
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 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 NMP or central M&E unit for SM&E/beginning to develop a data unit that includes data engineers, data scientists, data visualization experts/identifying a private sector entity that help provide these skills)	☐
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). This can also include establishing timely access to malaria data directly from the HMIS for the NMP in collaboration with the data units in the MOH.	☐
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 TA to catch logic errors)	☐
Admin1 (regional-equivalent)	
Registers for facilities and community health workers (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) 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) 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 - this includes activities in Community Health and intervention campaigns)	☐
Supervision of CHWs (training, traveling, administering supervision tools/checklists of community health workers)	☐
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 health care 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% 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 of surveillance and data support 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 strengthen 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."[252] 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 and timeliness 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 the clear determination and documentation of denominators. For example, activities targeting the district level should include the total number of districts (and population per district) in the country, the number of districts (and populations) intended to be reached by the PMI-funded intervention and those covered by other government or donor funds. In order to achieve the largest impact, emphasis should be placed on adding or expanding target areas.

To avoid potential confusion with support for sentinel sites or clinical strengthening, PMI requests only using the term RHIS strengthening (and not terms like "enhanced surveillance"or "malaria reference centers"). This does not mean that those sites will no longer be supported but that the MOPs should be clear in describing the overall strategy for RHIS strengthening efforts aimed at facilities, and how this will

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

be rolled out to encompass surveillance at district, regional, and national levels with an overall long-term goal of nationwide reach of RHIS strengthening efforts.

To improve data quality at facilities, in some cases, the efforts will include improving diagnostics in addition to strengthening routine reporting. Improving diagnostics is critical to obtaining accurate malaria data, and integrating PMI activities across technical areas (e.g., case management and SM&E) almost always makes sense. In the country MOP, activities that support strengthening diagnostics should be included under the case management section while RHIS strengthening activities should be included under SM&E. If the same partner is implementing both activities, the level of effort must be estimated and budgeted accordingly.

Note that in moderate/high-transmission settings it is not necessary or cost effective for a national surveillance system to track and monitor individual cases. Case registry, aggregation, and mapping is appropriate at the level of a community health worker or health facility; however at the district and national levels, aggregate data are more appropriate for following trends and malaria risk stratification for intervention planning in the moderate/high-transmission settings. (See 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 malaria case management and stock data for decision-making enables programs to target resources and saturation efforts, adjust case management practices, optimize stock management, and ultimately improve outcomes. In some PMI partner countries, Community Health Workers (CHWs) diagnose more than 50% 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 TWGs

- 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:

- Guidance for Community Health Workers Strategic Information and Service Monitoring: Guidance outlining a set of standardized indicators collected by CHWs on their activities and on the communities they serve.
- Model of a Community-Based Information System: Essential Components and Functions: Measure Evaluation created a model for community based information systems (CBIS) 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 CBHIS is and what should be in place to get it to the next stage.
- Best Practices in Strengthening Community Health Information Systems: Contains lessons learned on governance and leadership, defining data and information needs, and data collection and management
- Use of Community Health Data for Shared Accountability: Guidance: Guidance for practice document on how to use health data to be more responsible and accountable to communities for their health status.
- DHIS2 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 DHIS2 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.

Digital Health

The digitization of information has revolutionized all facets of daily life across the world. Not only are 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 response to this shifting landscape, PMI can support country 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 routine malaria prevention and treatment services are provided at facility and community levels (see Community Health section), as well as how campaign-delivered interventions are implemented (see **ITN campaign** section and **SMC section**), 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. Examples of potential use cases for digital tools are provided in the Table below.

Example Use Case	**Example Data Platform**
Collection of routine malaria diagnosis and treatment data at the community and/or facility level	DHIS-2 Comm Care
Collecting data on health worker performance through supervision visits	HNQIS Comm Care
Collection of campaign data on ITN or SMC distribution at the household level	DHIS-2 RedRose KoboCollect
Payment of campaign actors (distributors, social mobilizers)	Private sector cellular phone companies
Health facility or district level data review	DHIS-2

meetings to examine data quality and analyze trends	Zanzibar Coconut Surveillance System

As part of an effort to improve and automate healthcare services, the need for Digital Health Interventions (DHI) is growing. WHO and global health partners describe it as part of the different ways in which digital and mobile technologies are being used to support health system needs. DHI can be used for: Interventions for clients, Interventions for healthcare providers, Interventions for health system or resource managers and Interventions for data services (WHO-Classification of Digital Health Interventions v 1.0).

Note that effective DHI often requires significant investments in systems, platforms and human resources, if applied at scale. Understanding the landscape of country and partner investments in these domains is important when determining rational PMI contributions. For example, the Global Fund Information note for NFM4 grant applications specifically addresses digitization efforts that could be considered for funding, including "digitization of HMIS and data collection and the integration with national MIS" as well as support for "an integrated, multi-purpose digital platform that can be used for malaria campaigns as well as other campaigns and activities." Digital technology should be selected to address the specific data collection needs, the overall surveillance strategy, and the national telecommunication infrastructure and policies.

WHO Guidance on Digital Solutions for Malaria Surveillance

Surveillance is a core malaria intervention. Data standards, tools and curricula materials have been developed to support countries to strengthen and monitor national routine surveillance systems and to support use of data for decision-making in all transmission settings. These standards have been developed into malaria modules (focused malaria components and visuals) in DHIS2 for countries using this platform. These tools comprise:

- modules for burden reduction and elimination settings
    - aggregate module
    - case-based module
- modules for entomological surveillance and vector control interventions

The DHIS2 modules provide a set of data elements and indicators as well as validation rules and standard charts and tables presented in a set of dashboards.

The modules are accompanied by a guidance document and a curriculum to help programmes and participants understand and implement the content. The modules can be used either separately or in conjunction with one another depending on the type of public health responses being implemented.

The modules comprise a standard set of data elements and indicators, validation rules and dashboards for visualization of core epidemiological and data quality indicators, as charts, tables and maps. Routine reports and data exports can be easily generated for rapid dissemination of information to decision-makers. The modules, which are configurable and can be used either separately or in conjunction with one another, are accompanied by a guidance document and a curriculum for facility-level data analysis, to help programmes to understand the content and how the data can be used in practice.

Surveillance Assessments (Data Quality Assessment)

WHO, RBM SMERG (Roll Back Malaria's Surveillance Monitoring and Evaluation Reference Group) 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 S&I 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.[253],[254] PMI is continuing to support Operational Research to explore the possible utility of the ANC platform for collecting data on coverage of malaria interventions as well as malaria parasite prevalence. Initial results suggest that ANC data is able to capture trends in parasite prevalence with relatively high level of correlation as compared to data collected from children under 5.The correlation among coverage of malaria control interventions is continuing to be investigated.. 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 and/or malaria intervention coverage monitoring are encouraged to reach out to the S&I team.

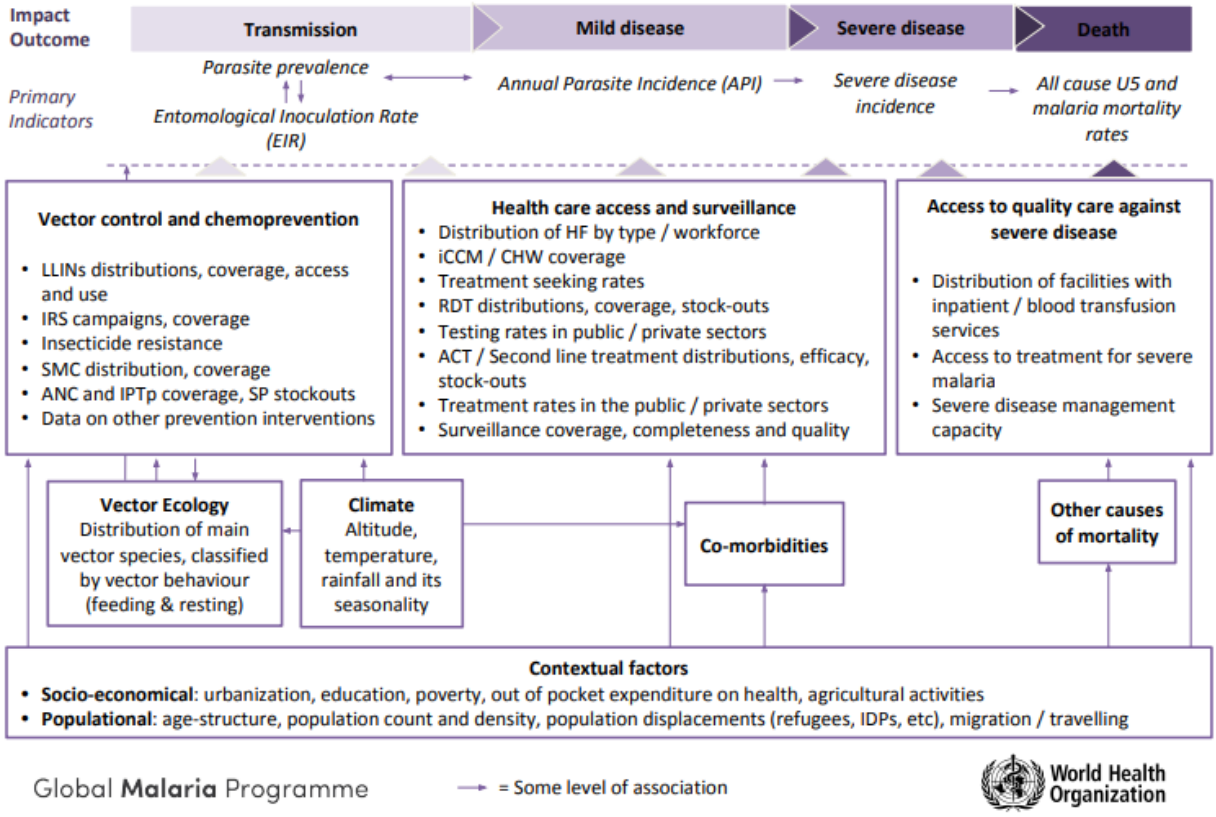
Malaria stratification mapping and sub-national tailoring of activities

Within most PMI partner countries, transmission intensity is diverse. There is growing global, regional and NMP emphasis on characterizing the varying malaria burdens in different geographical areas through stratification exercises and then tailoring deployment of intervention mixes based off of that stratification. These stratification activities use data to answer specific question(s) or help guide interventions and programmatic decision-making. A broad set of data can be leveraged to inform this stratification, as noted below in the WHO malaria framework for stratification.

[253] 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).

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

Figure 11: The WHO malaria framework for stratification



The *WHO malaria framework for stratification* is accessible at: *https://www.childhealthtaskforce.org/sites/default/files/2020-04/HBHI%20Response%20Element%202_Use%20of%20Strategic%20Information%20to%20Drive%20Impact%20%28A.%20Noor%29_iCCM%20Technical%20Consultation_07.2019.pdf*

For example, stratification may be conducted using the data shown in the WHO malaria framework above to define different transmission strata and then approaches such as the modeling of different intervention mix scenarios can potentially identify the most effective combination of interventions. Additionally, modeling of cost-effectiveness can then be done to optimize the impact of malaria resources. Cost is an important aspect as there will always be a limit on available resources and it may be easier to improve/increase the coverage of already chosen interventions with known costs rather than adding new interventions that require new or different platforms and systems with unknown cost structures.

Currently, many stratification exercises have used both survey prevalence data and HMIS incidence data. When the HMIS incidence data quality is good and continuously monitored and strengthened, it is preferable to use such a dataset to derive the strata. This is because HMIS data is more timely, more

geographically granular, and inclusive of more age groups. To help monitor smaller changes in malaria burden, and because different mixes and intensities of interventions may be required as geographic areas progress through WHO's "very low" stratum towards elimination, PMI suggests calculating some additional strata when incidence falls below 100 cases/1,000/year to monitor progress and trends in elimination across PMI partner countries. The elimination team has proposed these strata, which are noted below, however countries should consider the distribution of their own incidence data to ensure meaningful categories for district level incidence stratification. As further described in the Elimination Technical Team guidance, tracking of absolute case numbers is critical for programs nearing elimination to help inform the operational feasibility of case investigation and response efforts

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, tailoring should incorporate health systems, ecological, entomological, and behavioral data in order to determine the appropriate package of malaria interventions and tailor malaria prevention activities to specific settings.

In recognition of stagnating progress towards achieving 2020 malaria reduction objectives laid out in the Global Technical Strategy (GTS), WHO launched the High Burden High Impact (HBHI) initiative in 2018. The HBHI approach includes targeted support to India and the ten highest burden African countries to garner political will to reduce the toll of malaria, use strategic information to drive impact, develop better guidance, policies and strategies, and improve coordination of support for national malaria responses. A key pillar of the strategy is enhanced surveillance and the local use of local data. HBHI provides support to countries to stratify malaria risk, use data to determine the optimal packages of interventions and, in turn, include these within National Strategic Plans, prioritize intervention packages based on available resources and monitor the impact of these intervention packages. Supported activities include sub-national risk stratification and tailoring (SNT) exercises. The 11 countries initially targeted for HBHI (Nigeria, DRC, Mozambique, India, Uganda, Burkina Faso, Ghana, Niger, Cameroon, Mali and Tanzania) were those with the highest malaria burden determined by the number of malaria cases in a country, a factor of both population size and malaria endemicity. WHO has since expanded this

approach to target support for SNT to additional countries in recognition that it will be useful for all malaria endemic countries to ensure continued progress with the GTS elimination goals.
PMI country teams are encouraged to participate in SNT activities, as well as any other risk stratification or sub-national tailoring activities such as those related to developing an optimized and prioritized NSP. PMI-generated data, for example insecticide resistance data from entomological monitoring sites, can be valuable resources for these SNT 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. If you have questions about SNT, how to be engaged, what to look for, or your country is beginning the process, please reach out to the PMI S&I Team.

WHO Guidance on National Malaria Data Repositories

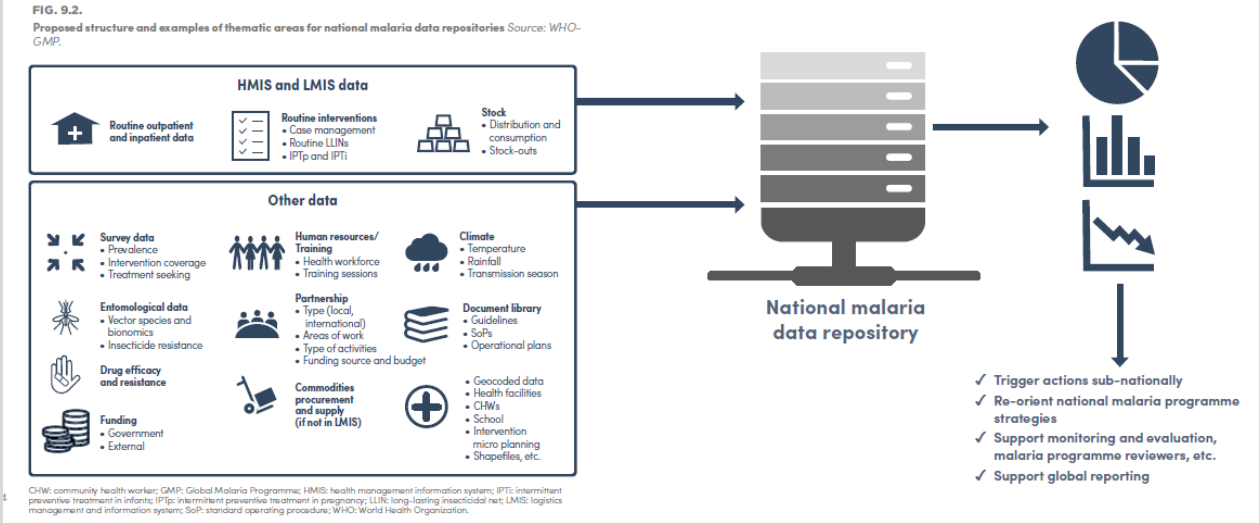
National Malaria Data Repositories (NMDR)

For countries to strengthen and sustain the practice of using data for decision-making, dynamic data repositories are necessary at national and sub-national levels. These platforms should be linked and geographically aligned to national routine systems and should integrate efficacy, household survey, programmatic, eco-climatic, social, behavioral and cultural data to enable routine operations, along with detailed annual sub-national programmatic reviews and, where necessary, stratification to further tailor interventions and response, while taking into account gender, human rights and equity considerations. Building a sustainable data repository infrastructure and the infrastructure of the technical capacity of staff on data management, for data analysis and interpretation is the overriding need in order to enable programmes to use surveillance information effectively.

WHO has been working in coordination with national health management information systems (HMIS) departments of ministries of health to establish structured dynamic databases that support NMPs subnationally to implement targeted malaria activities informed by clear stratification, to monitor disease trends, to effectively respond to epidemics, to evaluate programme performance and to develop national strategic plans.

These national data repositories are developed either as a part of WHO-supported national health observatories or as a direct service provided by the HMIS to disease programmes. GMP has developed an easily adaptable repository structure in DHIS2 with guidance on relevant data elements and indicators, their definitions and computation to cover key thematic areas. So far, work to develop these databases has started in Ghana, Mozambique, Nigeria, Uganda, and the United Republic of Tanzania.

Figure 12. Proposed Structure and Examples of Thematic Areas for National Malaria Data Repositories



NMDR Implementation Plan - Nigeria Example

NMDR is an interactive data repository necessary at national and sub-national levels for data storage, data validation, and analytics. For example, NMEP Nigeria is benefiting from the use of NMDR where it has been used for data storage, data validation, and analytics and automated generation of customized outputs such as dashboards and bulletins for tracking programme implementation and timely use for decision-making. The Nigeria NMDR is also structured to warehouse not only the routine data but also non-routine data such as climate data imported from M-DIVE to NMDR quarterly. Hence, it enables data import and easy retrieval when required for programmatic decision making or preparation of strategic plans/documents in line with the HBHI approach.

Figure 13. Recommended Process and Core Requirements to Develop a National Malaria Data Repository

M-DIVE Platform

To optimize data-driven decision-making, PMI has developed and continues to expand a cloud-based Malaria Data Integration and Visualization (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. Additionally, M-DIVE harnesses and integrates both HMIS and non-HMIS datasets linked to open source data science applications that allows PMI technical team to perform basic and advanced data analytics to better guide PMI's business operations and timely decision making. It also offers the required metadata standard and interoperable opportunities that are beneficial to the country's NMDR, HMIS and LMIS.

M-DIVE platform ensures a regular update of all various types of data for use by PMI, NMPs and other malaria stakeholders once they have the required log-in credentials. Currently, MDIVE has the following datasets: HMIS/DHIS2 (Monthly service delivery data), LMIS (Monthly health logistics data), Commodity Procurement, Funding Data, Health Survey Data, Health workforce, Health facility location, Climate (weekly refresh), Procurement Planning and Monitoring Report for malaria (PPMRm), Population and Shapefiles of geographical areas for PMI focused countries.

PMI takes data security and ownership very seriously. Data submitted by countries will not be shared outside of PMI (in-country teams and HQ) without the approval of the host country governments. These data will be combined with data that are housed at PMI-HQ or available publicly (i.e. PMI financial data, PMI-procured commodities, Satellite Imagery, Climate, DHS, MIS, etc.) to develop the dashboard reports. NMPs also have access to the underlying raw datasets behind QR dashboards for their respective country.

M-DIVE provides access and storage to geographically aligned datasets that are challenging to retrieve and/or process (i.e., satellite-derived population and climate). The geographical alignment of the datasets allow the disparate datasets to be linked and analyzed together for improved programmatic insight. M-DIVE also provides a data science platform with a suite of computing capabilities that countries and technical teams can take advantage of to test out new visualizations and analytics, which can generate ideas for country-owned systems and repositories.

Please contact Alaine Knipes or Misun Choi to begin the process of creating an account, which begins with signing a non-disclosure agreement (NDA).

Population-based surveys

As mentioned above and depicted in **Figure 12**, countries are facing a wide spectrum of data needs, data collection methods, and 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 SM&E investments in surveys are outlined below.

National-level household surveys

For PMI S&I needs, conducting a national-level household survey, within established survey timelines set by the Ministry of Health and other partners, is recommended to assess coverage of interventions and, when needed, estimates of malaria prevalence and ACCM. For more information on the standard indicators available from household surveys, there is a Global Health eLearning course available: https://www.globalhealthlearning.org/course/measuring-malaria-through-household-surveys

In moderate- to high-transmission areas, a survey every 2-3 years might be appropriate; in low-prevalence areas, an interval of 3-5 years would be more acceptable. In general, timing between survey iterations should allow for interventions and/or policy changes to produce measurable change. The type of national-level household surveys supported by PMI will generally be a MIS, DHS, or MICS that includes the standard malaria module. While PMI has typically funded an MIS in full or in partnership

with the Global Fund, the contribution from PMI to a DHS or MICS has typically ranged from $350,000-$500,000 but there are increasing requests from missions for larger contributions to the DHS or MICS. In light of these requests, the PMI contribution to the DHS or MICS should be comparable to the contributions from other health elements (MCH, PRH, NUT, etc.) at the country mission. In recent years, the frequency of such surveys has increased, 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 NMPs and partners are requesting that national-level household surveys be expanded to obtain estimates with sufficient statistical power for sub-regions or population sub-groups (e.g., school-age children or people over 15 years of age). Per RBM SMERG guidelines, PMI has supported surveys with sample sizes large enough to estimate coverage of interventions by malaria transmission zones as defined by the Mapping Malaria Risk in Africa climate suitability index (usually 3-5 zones per country). To obtain reasonable estimates for sub-regions or for sub-populations outside of RBM-SMERG-recommended ones, sample sizes and survey complexity and cost will increase. These concerns, in addition to on-going efforts to ensure that the quality of survey data are maintained, PMI and RBM-SMERG currently do not support such survey expansions. If the NMP and/or PMI country team believes it needs such estimates and is requesting PMI support, the PMI in-country team is asked to consult with the PMI Headquarters S&I 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 6-59 months of age in countries with a national prevalence estimate of >3%. In general, PMI does not support parasitemia testing during household surveys outside of this age group, with the following considerations:

- PMI does not recommend parasitemia testing below six months of age. The number of children under six months of age that test positive for malaria parasites would be very small.
- Adding other age groups (i.e., school-age children, pregnant women) to be tested would make the survey process more labor-intensive and risk compromising the quality of the survey.
- Gaining access to school-aged children (5-14 years old) can be logistically difficult and costly. Often these children are at school when the surveyors come by the house, requiring repeat visits. The children that are at home may be the sick children, resulting in selection bias.
- Testing pregnant women for malaria parasites during household surveys raises ethical concerns and requires a much larger sample size to produce meaningful estimates. Survey protocols require appropriate treatment with ACTs for anyone testing positive for malaria during the survey. If women of reproductive age (15-49 years) are included in surveys, it presents the possibility of pregnant women in their first trimester (who do not know they are pregnant or are not disclosing they are pregnant) being treated with ACTs. WHO has just recently approved the use of AL for treatment of uncomplicated malaria in pregnant women in their first trimester, but wider scale use of ACTs in the first trimester is challenging due to drug-specific contraindications or lack of evidence. PMI supports the guidance provided in the RBM MERG Household Survey Indicators for Malaria Control document regarding the use of RDTs (http://www.rollbackmalaria.org/files/files/working-groups/MERG/Reference%20documents/tool_HouseholdSurveyIndicatorsForMalariaControl.pdf) . 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 6-59 month olds, PMI will support the survey (provided it has been approved by the PMI Headquarters S&I 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 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued**. Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains greater than 3% in other regions or districts.

Additionally, in lower burden countries where the national parasitemia estimate is below 5% 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 S&I 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 Headquarters S&I 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 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.[255] The standard malaria modules in the DHS, MICS, and MIS surveys are interchangeable. If concerns exist about the quality of any of these surveys, country PMI teams are encouraged to speak with the PMI Headquarters S&I Team in the early stages of survey planning.

Special cross-sectional surveys

Special cross-sectional surveys (e.g., post-ITN 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., ITN ownership after a sub-national ITN distribution campaign), or malaria burden in a sub-group of individuals (anemia and parasitemia in school-age children), or utilize malaria measures other than parasitemia or RDT (e.g., serology or PCR). **PMI only recommends these surveys when a clear and necessary programmatic question needs to be answered and no other suitable data source for addressing the question exists.** If the timing of a larger planned survey, such as DHS or MIS, coincides with the desired timing of a special survey, every effort should be made to utilize the planned DHS or MIS. Special surveys should be timed for optimal data collection based on the programmatic question they are intended to answer and should not be repeated annually.

[255] 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.

If special surveys are proposed in country MOPs, country teams should provide concise descriptions of the activity that outline the programmatic question, scope, scale, and timing of the survey, in addition to how the information would be used to improve program implementation. A clear determination should be made whether the survey proposed is operations research; and in such cases coordination with the PMI Headquarters Operational Research Committee should be done.

Nationally Represented Health facility-based surveys

Nationally-representative health facility surveys (HFS) are intermittent, comprehensive evaluations of health system function and are primarily used for program monitoring: establishing a baseline and assessing which aspects of the program require intervention or policy change, and then monitoring changes in relevant indicators after the intervention or policy has been implemented. Health facility surveys are useful in situations where routine information systems and household surveys do not provide all of the necessary information on case management practices, system readiness, and training and supervision to meet programmatic needs of the NMP or PMI. There is currently no standard malaria-specific HFS. Health facility surveys 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 health facility surveys. For example, discrepancies between actual case management practices and HMIS reporting are best investigated through smaller-scale investigations than through a nationally-representative HFS.**

Purpose: To collect information on factors that affect case management service delivery such as commodity availability, patient flow, lab capacity, health worker training, experience and practices, supportive supervision needs and patient perceptions.

Methodology: HFS typically captures cross-sectional data from health facilities on several aspects of the health system including availability of commodities, appropriateness/quality of case management, data reporting, record reviews, diagnostic capacity, health worker training, and other indicators critical to case management for children and adults, across all health areas. The type of information required, the level of detail, and other factors will determine the appropriate HFS methodology to be used. A HFS may also include assessment of data quality and reporting, although it is not part of currently available, standard HFS protocols.

To the extent possible, facility surveys should ensure a level of standardization across a core set of indicators with some level of tailoring for country needs.

Scope: Endemic countries should consider nationally representative HFS. In cases in which PMI is only working in part of the country or only parts of the country are endemic, sub-national HFS can be considered.

Timing: As a general rule HFS should not be repeated more than every 2-3 years, depending on the information required, and not be made routine. More frequent HFS may be considered on a case-by-case basis but there should always be enough time between HFS to allow for interventions or policy changes to produce measurable changes. When possible, HFS should be carried out during the malaria season to obtain the most reliable assessment of malaria service readiness.

Costs: Costs will vary widely, from $150,000 to over $1 million depending on the sample size and method. In general, because health facility surveys can be very comprehensive and include many other health delivery systems, PMI should strive to work with other health sectors in the mission and other donor partners to co-finance an HFS.

Integration: Children under five years of age with fever are evaluated in health facilities using integrated case management protocols. When a HFS includes an observation or re-examination module, case management of children should be observed and cases re-examined using an integrated protocol. Commodities and health worker knowledge should be included in any 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 (see list of surveys provided below) 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 S&I 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 PMI S&I and Case Management Teams for additional information.

Examples of health facility surveys

There are several types of health facility survey protocols, which vary in the aspects of the health system on which they focus, the overall cost and complexity, and how the results can be interpreted. For PMI purposes, HFSs that produce estimates quickly – within three to six months – should be favored as commodity and case management data become increasingly non-actionable if there are significant delays between the survey and the sharing of results. Listed below are global, health facility survey tools that include questions on multiple health areas and the national system. There is currently no standard malaria specific HFS but the PMI Case Management and S&I teams are discussing the possibility of a standardized malaria specific HFS tool along with recommended use cases and frequency.

End-Use verification tool

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

Service provision assessment (SPA)

Note: At the time of updating this guidance document, a process to revise the SPA and develop a standardized and improved Quality of Care (QoC) survey is underway through the DHS-8 Program. The goal is to field the new tool in 2023 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. A SPA is one of the most complex facility surveys and collects data from a large sample (often in the hundreds) of health facilities on the readiness and availability of specific health services and commodities as well as quality of services. The SPA focuses on nine key services: (1) child health; (2) maternity and newborn care; (3) family planning; (4) sexually transmitted infections; (5) HIV/AIDS; (6) malaria; (7) tuberculosis; (8) basic surgery; and (9) non-communicable diseases. The SPA includes assessment of health provider practices in each of the key

services through direct observation, health worker interviews and exit client interviews. Instruments typically used in a SPA are:

- Health worker interview
- Caretaker exit interviews
- Health worker observation protocols
- Facility inventory

The tool can be found at: http://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm

Service availability and readiness assessment (SARA)

Service availability and readiness assessment (SARA) surveys are designed to assess and monitor the service availability and readiness of the health sector and to generate evidence to support the planning and managing of a health system. The SARA generates tracer indicators of service availability and readiness. The SARA has been developed by WHO in conjunction with global partners to fill critical data gaps in measuring and tracking progress in health systems strengthening. While the SARA is not malaria-specific, it is possible to include a patient exit interview module to assess malaria case management practices; an optional data quality assessment module can also be added. Instruments typically used in a SARA are:

- Staffing matrix
- Inventory of inpatient and observation beds
- Facility infrastructure audit
- Inventory of available clinical services
- Diagnostic capacity assessment
- Inventory of medicines and commodities
- Interviewer's observations

The tool can be found at: https://www.who.int/data/data-collection-tools/service-availability-and-readiness-assessment-(sara)?ua=1
Link: Service availability and readiness assessment (SARA) (who.int)

Integrated management of childhood illness health facility surveys (IMCI HFS)

Integrated management of childhood illness health facility surveys collect health facility data exclusively on childhood diseases including pneumonia, diarrheal disease, and febrile illnesses (malaria, including trigger points for management and referral for severe malaria). This survey produces findings within 12 weeks of start of implementation and can be adapted to different sample sizes. Instruments typically used in the IMCI HFS are:

- Health worker observation checklist
- Exit interview – caretaker of child
- Re-examination of sick child
- Equipment and supply checklist
- Health worker interview (optional)

The tool can be found at: https://www.who.int/publications/i/item/health-facility-survey
Link: Health facility survey (who.int)

Evaluation

Evaluation is a critical component of any national malaria control program and should be integrated into national SM&E strategic plans. PMI supports both program and impact level evaluations at the country level, however there are a number of considerations to take into account when programming funds for evaluation activities.

As part of overall malaria control impact evaluations, PMI generally does not support evaluations aimed at establishing/researching a WHO-recommended specific intervention's impact on morbidity or mortality (WHO recommended malaria interventions include but are not limited to IRS, ITNs, IPTp, Case Management, and SMC). PMI is based on a principle of implementing **already-proven interventions** and thus does not support individual country programs to test/research any one intervention or package of interventions to assess its impact on malaria morbidity or mortality outside of approved Operations Research (see Operations Research section). Also, given PMI's success in increasing coverage of multiple interventions across countries, conditions do not lend themselves easily to evaluate the impact of single interventions.

As interventions are being scaled-up, PMI encourages evaluations in countries where these interventions are not resulting in the expected outcome. These evaluations can help to identify ways to improve the effectiveness, coverage, or service delivery of individual interventions.

Program evaluation

There may be a number of times in a program's lifecycle when an evaluation is necessary to inform further programming decisions. Some examples of when a program evaluation might be useful include evaluating a pilot to inform decisions about scale-up of interventions, evaluating the effectiveness of one programmatic approach against another, or evaluating project achievements at the end of an activity before a programmatic redesign process.

Malaria program reviews per WHO methodology include program evaluation components and are generally supported by PMI. Malaria program reviews should be carefully planned and coordinated with all partners (ideally timed to precede a country's new 5-year National Malaria Strategic Plan), last less than one year, not be repeated more frequently than every four years, and produce actionable data and information. No more than $100,000 of PMI resources should be budgeted in total for a malaria program review.
https://www.afro.who.int/publications/practical-manual-malaria-programme-review-and-malaria-strategic-plan-midterm-review

Impact evaluation

Evaluations of impact are generally good practice; however, impact evaluations are dependent on country need and will most often focus on the impact evaluations of specific interventions or packages of interventions. 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 (Framework for Evaluating National Malaria Programs in Moderate- and Low- Transmission Settings, Guidance for Evaluating the Impact of National Malaria Programs in Highly Endemic Countries) should be used to ensure consistency and comparability across time and countries. Evaluations of impact should be transparent and participatory. Many stakeholders, both within and outside of malaria control activities, should be encouraged to participate in the design, analyses, and production of reports.

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 10: SM&E Appendix 1: Minimum System Requirements at Various Health System Levels During Control and Elimination Phases

	Control (e.g., TPR >5% amongst all febrile patients)	Elimination (e.g., TPR <5% amongst all febrile patients)
Community Health Worker	Test and treat malaria appropriately Document and report all cases Receive supervision and feedback	Test and treat malaria appropriately Document and report all cases Receive supervision and feedback
Health Facility	Test and treat malaria appropriately Document malaria cases, diagnostic testing results, and case management in registers Cases are graphed monthly to quarterly to identify trends Aggregated data transmitted monthly to district and higher ideally electronically Receive supervision and feedback	Test and treat malaria appropriately Registers of individual malaria cases, diagnostic testing results, and case management documented Cases are graphed daily to weekly to identify trends that may require focal response Data transmitted weekly to district and higher ideally electronically Receive supervision and feedback
Admin 1 and 2 levels	Aggregate data of uncomplicated cases, severe disease, and deaths summarized monthly to allow an understanding of the burden by district and health facility catchment levels Analysis of data Data used to set priorities for interventions	Aggregate case and death data summarized weekly or monthly to allow an understanding of the needs by health facility catchment or village level to help set priorities for interventions Register of severe cases and deaths maintained and case investigations performed to identify program breakdowns and needs Provide supervision to health facilities and receive feedback
National	Monthly to quarterly tabulation of cases and deaths to assess control efforts and prioritize activities Analysis of data Data used to set priorities for interventions	Weekly tabulation of cases and deaths to assess control efforts and prioritize activities

SM&E Appendix 2: Key reference manuals

1. WHO Malaria Surveillance, Monitoring & Evaluation: A Reference Manual
2. Household Survey Indicators for Malaria Control (English)
3. Household Survey Indicators for Malaria Control (French)
4. Monitoring and evaluation of malaria-related routine data during the COVID-19 pandemic (English)

SM&E Appendix 3: Key acronyms and definitions

ACCM- All-Cause Child Mortality
ANC- Antenatal Care
BMGF- Bill and Melinda Gates Foundation
CHW- Community Health Worker
DCH- Digital Community Health
DHI- Digital Health Interventions
DHIS-2- District Health Information System 2
DHS-8 - Demographic Health Survey - 8 Project
DHS- Demographic Health Survey
FETP- Field Epidemiology Training Program
HBHI- High Burden High Impact
HFS- Health Facility Survey
GMP- Global Malaria Programme
GTS- Global Technical Strategy
HFS- Health Facility Surveys
HMIS- Health Management Information Systems
IAA- Interagency Agreement
IDSR- Integrated Disease Surveillance and Response system
IMCI HFS- Integrated Management of Childhood Illness Health Facility Surveys
IRS- Indoor Residual Spraying
ITN- Insecticide Treated Nets
MCH- Maternal and Child Health
M-DIVE- Malaria Data Integration and Visualization platform
MICS- Multiple Indicator Cluster Survey
MIS- Malaria Indicator Survey
MOH- Ministry of Health
MOP- Malaria Operational Plan
NFM4- New Funding Model 4
NMP- National Malaria Program
NMDR- National Malaria Data Repositories
NMP- National Malaria Program
NUT- Nutrition
NSP- National Strategic Plan
PEPFAR- President's Emergency Plan for AIDS Relief
PRH- Population, Reproductive Health
QoC- Quality of Care
RBM- Roll Back Malaria
RBM SMERG- Roll Back Malaria's Surveillance Monitoring and Evaluation Reference Group
RDT- Rapid Diagnostic Test
RHIS- routine health information systems
SARA- Service Availability and Readiness Assessment
S&I- Surveillance and Informatics
SPA- Service Provision Assessment
SM&E- Surveillance, Monitoring, and Evaluation
SNT- Sub-national Tailoring
TPR- Test Positivity Rate
UNICEF- United Nations Children's Fund
USG- United States Government
WHO- World Health Organization

ELIMINATION

New/Key Messages

Strategy: The PMI Strategy 2021–2026 includes an elimination-focused objective: To accelerate towards national or subnational elimination in 10 countries with at least one country reaching elimination. 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%. Within the PMI portfolio, the countries in the Greater Mekong Sub-region are pursuing national elimination efforts, whereas the following countries are working at subnational levels: Ethiopia, Kenya, Madagascar, Senegal, Tanzania/Zanzibar, Zambia, and Zimbabwe. These countries 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 2024 MOPs.

In countries where malaria burden varies significantly, and thus sub-national elimination is being pursued, priority for PMI funding should be given to supporting interventions to further reduce mortality and morbidity in high burden areas. However, in such settings, limited support for elimination activities can be considered by PMI country teams, but should be balanced against the need to scale up core control interventions to achieve PMI's primary objectives to reduce morbidity and mortality.

New Tools/Resources:

- Given the sample size requirements in settings with very low transmission, high quality, randomized, controlled trials to evaluate the effectiveness of non-standard interventions are likely not feasible in elimination settings. However, WHO and PMI recognize the value of less robust, non-randomized studies to guide policy recommendations for non-standard interventions that may accelerate elimination. Controlled before-and-after studies, interrupted time series and/or case-control studies often used in the study of rare diseases may provide evidence needed to influence PMI policy for the adoption of new interventions in the context of elimination.
- Tafenoquine is now approved by the Australian Therapeutic Goods Administration for children above 2 years for the management of *Plasmodium vivax*. Please see the Case Management section for details.

- Although PMI limits the use of topical repellents to operational research or program evaluation (OR/PE), the exception is in elimination settings and as part of a larger package of interventions for high-risk, and generally mobile populations. 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 Prequalification Team Unit, procurement is limited to products registered by the US EPA. Note additional environmental requirements may need to be met to procure and distribute topical repellents. A PMI IEE was approved for topical repellents; please see the Elimination and Vector Control teams if a country is considering procuring topical repellents.

- In settings approaching elimination or post-elimination, reactive drug administration and reactive case detection activities are recommended by WHO and can be implemented, ideally with on-going monitoring and evaluation to ensure needed evidence generation.
- WHO released a new online training module for elimination which can be downloaded and adapted to the country context.

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. 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."

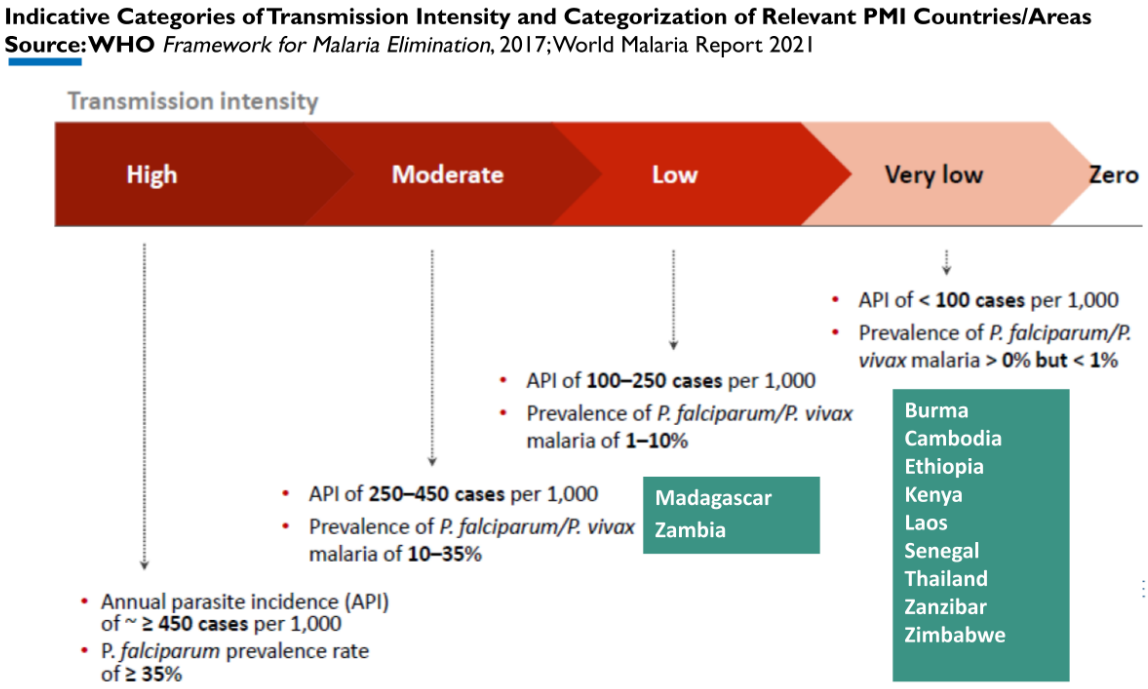
From the last *PMI Strategy 2015–2020,* PMI met its elimination objective: *To assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination by 2020*. The current PMI Strategy 2021–2026 again includes an elimination-focused objective: To accelerate towards elimination in 10 countries and eliminate in ≥1 country. The objective aims to target low-burden countries and bring them toward national or subnational elimination, with at least 1 country achieving elimination. The criteria for PMI considering elimination support in a given country is 1. national (or subnational) parasite prevalence <5% 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 Sub-region are pursuing national elimination efforts, whereas the following countries are working at subnational levels: Ethiopia, Kenya, Madagascar, Senegal, Tanzania/Zanzibar, Zambia, and Zimbabwe.

Malaria elimination builds on the foundation laid by intensive malaria control, with universal coverage of efficacious interventions for vector control among populations at risk and effective case management 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 high-quality health management information system (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, subnational areas, and communities are situated at different points on the path towards malaria elimination, and their rate of progress will differ and depend on the level of investment, biological determinants (related to the affected populations, parasites, and vectors), environmental factors, and the strength of health systems, as well as social, demographic, political, and economic realities. 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 14**). This reorientation emphasizes that all countries, regardless of where they lie on that continuum, should have a long-term vision of malaria elimination. This Figure 14 from WHO spans a wide range of transmission intensities. Most of the PMI eliminating countries fall under the very low transmission category, with the exception of Madagascar and Zambia which each have subnational areas targeted for elimination.

Figure 14. Indicative Categories of Transmission Intensity and Categorization of Relevant PMI Countries/Areas



Several PMI countries have now set national or subnational goals of malaria elimination, scaled up control measures, and are improving their routine malaria information systems (see **Figure 15**). Figure 16 notes the percentage of districts with active elimination activities.

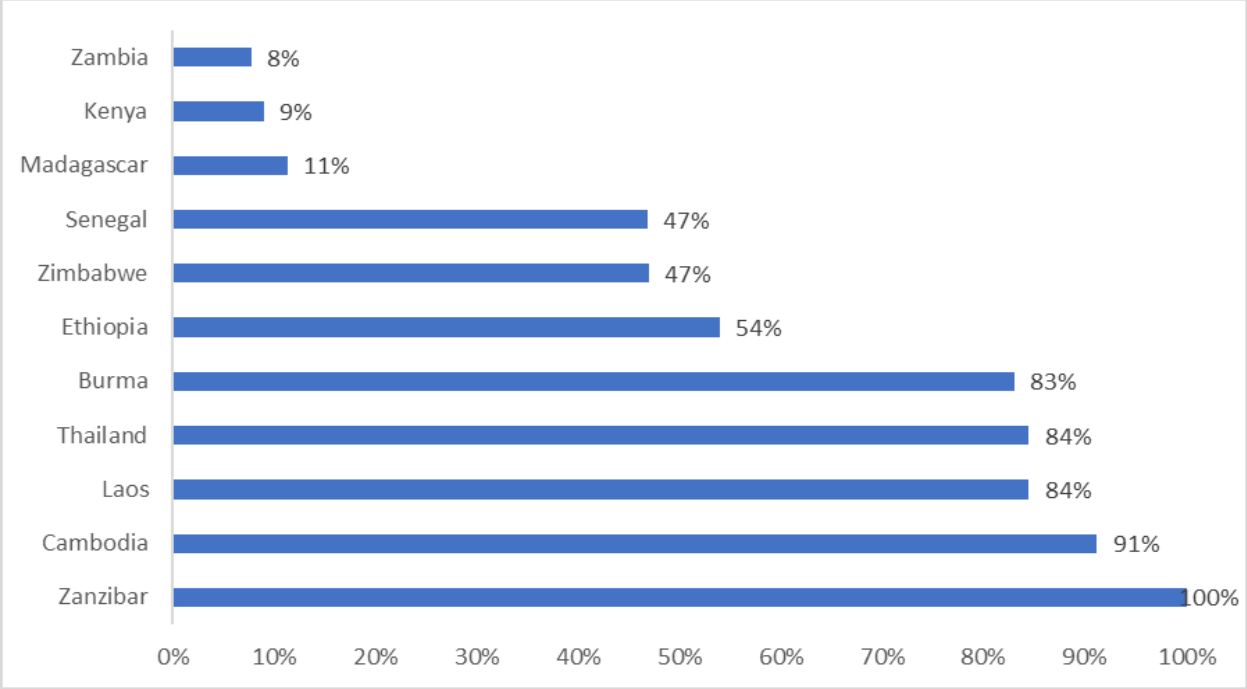
Figure 15. Tracking Progress and Capacity in Reaching Elimination in PMI-supported Countries/Areas

	POLICY		IMPLEMENTATION		ROUTINE DATA				
Country/Area	Pre-/ Elimination Strategy	Risk Strati-fication	Cases investigated	Foci investigated	API*	Test Positivity Rate*	Case Confirmation Rate*	Method used to report incidence#	HF Reporting Rate^^
Thailand	National	Recent	National	National	<1	<1	100	Method 3	100^
Myanmar/Burma	National	Recent	Sub-national	Sub-national	1-10	<5	101	Method 1	not reported
Lao PDR	National	Recent	National	National	1-10	<1	100	Method 1	100
Zanzibar	National	Recent	National	National	1-10	<5	100		99
Cambodia	National	Recent	Sub-national	Sub-national	1-10	<5	100	Method 1	99
Ethiopia	Sub-national	Recent	Sub-national	Sub-national	10-100	5-50	94	Method 1	89
Senegal	Sub-national	Recent	Sub-national	Sub-national	10-100	5-50	98	Method 1	98
Kenya	Sub-national	Recent	Not done	Not done	10-100	5-50	53**	Method 2	98
Zimbabwe	Sub-national	Recent	Sub-national	Sub-national	10-100	5-50	100	Method 1	95.5
Madagascar	Sub-national	Recent	Sub-national	Not done	>100	5-50	100	Method 1	97
Zambia	National	Recent	Sub-national	Sub-national	>100	54.5	93	Method 2	93

*Data source: WMR 2021, Annex 5H
**KE reported double counting, but the confirmed case count has not been corrected
Method used by WHO to estimate malaria burden: (Method 1) used for Low Transmission countries. Reported cases counts are adjusted; (Method 2) used for High Transmission countries. Modeled estimates based on parasite prevalence; (Method 3) used for Elimination Settings. Numbers reported by NMPs are reported without any adjustment (WMR Annex 1 2021)
^Data source: MOP FY22

Source: API, TPR, and CCR are from WHO *World Malaria Report* 2021.

Figure 16. Districts with active elimination activities, 2022*



*Data Source: PMI FY23 Country Profiles. Please note that districts that have already eliminated malaria are not included, e.g. for Thailand

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 indicators: ITN/IRS coverage, treatment-seeking within 24 hours of fever onset, and malaria prevalence and incidence*
    - *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 case management interventions.
- A surveillance, monitoring, and evaluation system able to identify, investigate, and control malaria foci, 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 community health worker (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 ministry of health to support elimination efforts, supported by a strategic plan*

PMI and other partners have developed new tools including Ethiopia's Malaria Elimination Baseline Assessment Tool and UCSF's District-level Readiness for Elimination of Malaria Tool (DREAM-IT)[256] that are intended to systematically assess the system and human capacity readiness at national and sub-national levels to move towards elimination. An evaluation of the technical and operational situation using such tools is an essential first step in planning and implementing elimination activities. The findings of assessments using such tools will provide programs with necessary information on what areas require further strengthening, which will enable better prioritization of PMI and country resources. Anyone interested in learning more about these tools and its potential adaptation and use in other countries can contact the PMI Elimination 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 operational research to determine cost-effective and feasible elimination approaches are permitted. **In countries where malaria burden varies significantly and sub-national elimination targets are being pursued in some geographic areas, priority for PMI funding should be placed on supporting control interventions to further reduce burden and transmission in the higher transmission areas.** Furthermore, these control efforts focused on high transmission areas will be crucial in limiting the exportation of cases to elimination areas within the country.

[256] http://www.shrinkingthemalariamap.org/tool/district-level-readiness-elimination-malaria-tool-dream-it

Integrated Approaches to Malaria Elimination and Response

Malaria Stratification Mapping and Sub-national Tailoring of Interventions

Globally, malaria programs are moving away from "one-size-fits-all" approaches. Stratification mapping and sub-national tailoring can help programs with geographically classifying areas and then using data and contextual information to optimize which interventions are used and to target them to areas where they are needed and where they will be effective to maximize program efficiency. While all malarious areas should continue supporting malaria case management and malaria surveillance, sub-national conditions should inform selection of other malaria-related interventions. Additional information on stratification mapping and sub-national tailoring can be found in the Surveillance & Informatics Technical Guidance.

Within most PMI countries, transmission intensity is diverse. WHO's 2017 Malaria Elimination Framework[257] defines malaria transmission strata using annual parasite incidence (API) or prevalence of malaria caused by *P. falciparum*. Most countries can now assess annual malaria incidence sub-nationally using data from HMIS. Data quality (completeness, accuracy) should be monitored, but generally strata should be created using HMIS incidence data rather than survey-derived prevalence data because it is more timely, more geographically granular, and inclusive of more age groups. To help monitor smaller changes in malaria burden, and because different mixes and intensities of interventions may be required as geographic areas progress through WHO's "very low" stratum towards elimination, PMI suggests calculating some additional strata when incidence falls below 100 cases/1,000/year. Within MDIVE, PMI uses standardized incidence cut-offs for all PMI countries which may facilitate clearer, more granular visualization of the range of malaria transmission intensities for eliminating countries. To monitor progress and trends in elimination across PMI partner countries, PMI will use the following categories for district level incidence stratification:

Table 11. 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

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

Although malaria transmission intensity (e.g., incidence) should form the foundation of stratification, as transmission decreases, stratification should also incorporate ecological, entomological, and SBC data to determine the appropriate package of malaria interventions. Furthermore, for programs nearing elimination, tracking of absolute case numbers will be critical in informing the operational feasibility of investigating and responding to cases and ultimately documenting zero cases. WHO's High Burden High Impact[258] 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.

Ideally, sub-national incidence will be monitored on an on-going basis to inform program decisions. Formal re-stratification and re-assessment of the intervention mix will be needed less frequently to inform strategic direction and funding decisions.

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 are 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 ITNs 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

[258] http://allianceformalariaprevention.com/wp-content/uploads/2020/01/4.-High-Burden-to-High-Impact-How-stratification-can-improve-targeting-of-vector-control-interventions-WHO.pdf

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 ITNs to farm/plantation owners to distribute to their workers
- Providing long-lasting insecticidal hammock nets (LLIHNs) for migrant/outdoor workers
- Setting up farm/plantation/forest clinics/workers or training mobile or work-site malaria workers
- Training taxi drivers to provide malaria messages and referral to services to migrant populations
- Using innovative sampling (e.g., snowball, respondent-driven, and time-location sampling) to conduct surveys of mobile/migrant populations
- Developing SBC materials in languages appropriate to the targeted population, including dual language or low literacy materials for use in cross-border settings
- Establishing additional health posts or community health workers at borders
- Employing novel surveillance approaches to capture testing and treatment data so that these high-risk groups are accounted for in monitoring and evaluation efforts

Foci Investigation and Response

As malaria transmission declines, recalcitrant foci of transmission may remain. 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.

There are practical challenges faced when applying these definitions to some elimination settings. For example, the location where malaria transmission takes place may not be easily accessible or meet the criteria of being a "defined and circumscribed area", e.g., where transmission occurs in forests or among mobile populations. Consequently, foci response activities may need to be implemented in areas where there is no immediate evidence of transmission (e.g., villages where forest-goers reside). Under such circumstances, it is important to coordinate with the national malaria program (NMP) and partners to arrive at clear approaches and definitions of what constitutes a focus, assumptions involved, as well as appropriate interventions.

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. If conducted, reactive case detection should also include 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 ITNs, 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 ITNs 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 ITNs, RDTs and ACTs. Depending on the size of the focus and/or the number of cases, additional VMWs may be recruited to serve the population at risk. In addition to use of ITNs 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 ITNs and/or IRS, entomological investigations are required to identify the primary vectors, their susceptibility to insecticides used on ITNs or for IRS, their biting behaviors including the predominant times and locations of biting, and the distribution of potential larval habitats in the area, where possible. 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 ITNs 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 ITNs or IRS may require additional, non-standard interventions that may not be appropriate in a control context, where broad scale coverage is needed. These may include interventions such as mass drug administration or larval source management as the rubric of 'fixed, few, and findable' may be

less relevant in a severely circumscribed focus when the object is malaria elimination (See the Larval Source Management Section in the Vector Monitoring and Control Chapter for more information). The Malaria Behavior Survey in Low Transmission Settings[259] 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.

Non-standard Interventions for Residual Transmission

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[260,261], 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 sub-region 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 program evaluation. **PMI may provide support for program evaluation or operational research to determine the acceptability, feasibility, and effectiveness of non-standard interventions. Given the sample size requirements in settings with very low transmission, high quality, randomized, controlled trials to evaluate the effectiveness of non-standard interventions are likely not feasible in elimination settings. However, WHO and PMI recognize the value of less robust, non-randomized studies to guide policy recommendations for non-standard interventions that may accelerate elimination. Controlled before-and-after studies, interrupted time series and/or case-control studies in the study of rare diseases are often**

[259] The MBS for Low Transmission Settings will be piloted in CY2021 and will be ready for use in CY2023.

[260] 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 randomised trial. PLoS Med 17(8):e1003177. doi: 10.1371/journal.pmed.1003177.

[261] 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.

used and may provide evidence needed to influence PMI policy for the adoption of new interventions in the context of elimination. For the design of such studies, please consult with the Elimination Technical and Operational Research Management Teams.

In addition, where appropriate, PMI may partner with NMPs 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.**

Vector Control and Entomological Monitoring

Role of vector control in elimination settings

The common vector control interventions broadly scaled up in control areas – ITNs and IRS – should be targeted to areas where transmission is ongoing in elimination settings. It should be noted that even if a mosquito population shows tendencies to bite or rest outdoors, that indoor interventions can still have a significant impact on the population as a whole since indoor and outdoor biting 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 insecticide treated net or surface). The role of vector control will also be dependent on where cases are coming from (e.g., locally within the village or being brought back from elsewhere, e.g., the forest).

Reactive IRS in response to index cases or active foci has been given a conditional recommendation by WHO and is implemented in some elimination countries (e.gThailand). 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 would be considered cost-effective compared to standard IRS when the incidence of malaria was less than 2.0 to 2.7 cases per 1000 person-years. However, coverage of IRS in the two studies varied substantially and there remain questions around when and where reactive IRS is appropriate. To maximize available tools to countries approaching malaria elimination, PMI can support technical assistance for countries implementing reactive IRS in response to active foci as part of a malaria elimination strategy. Support for procurement of insecticides or direct implementation of

reactive IRS can be supported under OR/PE, if it is a country priority and resources allow. **Please consult with the Elimination Team and the Vector Monitoring and Control Team's IRS Teamlet for further guidance.**

Although no clear criteria exist for stopping ITN distribution, WHO recommends that vector control intervention coverage should be maintained at least until transmission has been fully interrupted (i.e., no indigenous cases) and, if feasible, beyond that point, to minimize the risk of reintroduction. If vector control measures are withdrawn, countries must ensure that malaria case surveillance systems are in place to monitor the situation closely.

Role of entomological monitoring in support of vector control

In high-transmission areas, longitudinal entomological monitoring via fixed sites is necessary and cost-effective given the likelihood of finding mosquito vectors at a particular site is high. Thus, the sampling location 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. 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 staff. The PMI Headquarters Vector Monitoring and Control Team will help advise for specific elimination settings. For further information on the needed components of entomological monitoring, refer to the **Entomological Monitoring** chapter.

Entomological monitoring and the prevention of reintroduction

Receptivity refers to the degree to which a certain place supports local malaria transmission, including in areas where malaria has been eliminated and could potentially be reintroduced. Measurement of receptivity has not been well defined although it has been recommended to use quantitative measures such as vectorial capacity, minimum thresholds for mosquito density, the reproductive rate of *Plasmodium* spp. or the parasite prevalence rate. Most of these are not feasible in elimination settings and many countries simply rely on the presence or absence of primary vectors as an indicator of receptivity, a proxy which is likely adequate for programmatic purposes.[262] However, reaching a wide geographic area represents a challenge for centralized entomological monitoring programs. PMI encourages countries concerned about the prevention of reintroduction to build entomological capacity at lower administrative levels and/or consider community-based surveillance. Cadres of staff trained in entomological monitoring working at the district level or below can conduct routine surveys for primary malaria vectors and are positioned to rapidly respond in the event of an outbreak. Note that while periodic surveys may overlook the seasonality of the primary malaria vectors, the establishment of fixed sentinel sites in elimination settings is not supported by PMI.

Malaria in Pregnancy in Elimination Settings

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

[262] Yukich J, Lindblade K, Kolaczinski J. 2022. Receptivity to malaria: meaning and measurement. Malar J 21(1):145. doi: 10.1186/s12936-022-04155-0.

control of malaria in pregnant women and ensure effective case management. PMI also considers pregnant women as an "easy access population" as a means of monitoring malaria transmission as transmission goes very low.

Countries proceeding towards elimination should continue to provide ITNs to pregnant women both through campaign distributions and through routine antenatal care depending on the country's distribution strategy. In countries, which do not currently implement IPTp (e.g. Ethiopia and the Mekong), ITNs are the only preventive measure that can be applied throughout the pregnancy. 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, 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 treatment and health care seeking for fever during pregnancy.

See the Malaria in Pregnancy chapter for more information.

Case Management in Elimination Settings

The Case Management chapter contains information relevant for diagnosis and treatment in all transmission settings. This section focuses on additional considerations for low transmission settings. As transmission decreases, it becomes essential to enhance case management to find all suspected malaria cases, confirm with a diagnostic test, treat all cases according to national treatment policies, conduct an investigation to collect case information, and determine the likely location of infection (i.e., local vs. imported), and report both testing results and case information. As noted in the new PMI Strategy Focus Area 2 of *Strengthening community health systems,* all PMI countries pursuing elimination are implementing access to malaria case management **for all ages** often delivered through a network of community health or village malaria workers.

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 available but their utility even in elimination settings is unclear. Although the hsRDT developed by Abbott detects the HRP-2 antigen and has a limit of detection of parasite density that is about 10–20 times lower than conventional RDTs, it misses a large proportion of subpatent infections identified by polymerase chain reaction (PCR). Overall, RDTs with a lower limit of detection will provide 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 malaria in pregnancy will need to be under the context of operational research or program evaluation. **Neither WHO nor PMI recommend the use of highly-sensitive RDTs for surveillance 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 or loop mediated isothermal amplification (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.

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. PMI should prioritize support to ensure these skills are retained in these settings.

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 understand that occasional expiration of small amounts of unused commodities is often unavoidable.

The need for rapid diagnosis, treatment, and response to malaria cases also necessitates quick and easy access to care for affected populations. In elimination settings, village or community health workers often become the foundation for both malaria case management and the subsequent investigations. Additional approaches, including mobile or migrant health workers, border clinics as in the E8 countries, health services provided in high risk settings (such as plantations in Cambodia or mining/forest camps) also have been used to facilitate access to care.

Treatment

Curative drug treatment of uncomplicated and severe malaria cases does not differ in elimination settings from areas of higher transmission. When moving towards elimination, additional efforts are recommended to ensure treatment adherence and clearance of infection. Though costly, directly observed therapy (DOT), often in a modified form where each morning dose is observed by a CHW or a family member can be considered. As an alternative to therapeutic efficacy monitoring, repeat testing with microscopy to document clearance of parasitemia after completion of treatment called integrated drug efficacy surveillance, is being used in some eliminating countries (particularly in the Greater Mekong Subregion, where treatment failures to ACTs have been identified).

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.**[263] Recommendations include administration of single dose 0.25mg/kg primaquine **(except pregnant women, infants aged <6 months, and breastfeeding women of infants aged <6 months)** on the first day of ACT treatment and with food to improve tolerability. Testing for G6PD deficiency is not required for this single-use, low-dose primaquine regimen but advice to individuals are given 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 settings with confirmed artemisinin resistance.[264] Currently, single dose primaquine in addition to an ACT are the first-line treatments nationally in all countries in the Mekong, Ethiopia, and Zanzibar and subnationally in low transmission districts only in Senegal 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.

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[263] Policy brief on single-dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria, January 2015: http://www.who.int/malaria/publications/atoz/who_htm_gmp_2015.1.pdf

[264] 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%. It is also reasonable to use a health facility test positivity rate of <5% as a threshold.

Treatment of P. vivax infections

Countries outside of tropical Africa on the path to eliminating malaria will often have proportionately higher levels of non-*falciparum* infections, particularly *P. vivax*. Appropriate 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.

See the Case Management chapter for more information on treatment of *P. vivax*.

Monitoring treatment efficacy

As the number of malaria cases decreases, it will be more difficult to recruit the minimum number of patients required to conduct therapeutic efficacy surveillance. Several countries in the Mekong, where drug resistance is a major concern, have shifted to integrated drug efficacy surveillance (iDES) as a novel approach which incorporates drug resistance monitoring into routine case-based surveillance and response. Routine monitoring for parasite clearance outside of the Mekong is conducted by some, especially those that hospitalize all malaria cases, but not all eliminating countries.

Chemoprevention and Test and Treat Strategies

In June 2022, WHO released updated guidelines on chemoprevention approaches and interventions in the final phase of elimination. Although WHO continues to conditionally recommend the use of MDA to reduce transmission of *P. falciparum* in very low to low transmission settings and to reduce transmission of *P. vivax*, chemoprevention approaches, e.g., MDA will need to carefully consider the objectives and resource availability and be conducted in the context of OR or program evaluation to ensure rigorous implementation and evaluation. PMI countries interested in using MDA should consult with the relevant PMI Headquarters teams (Elimination, Chemoprevention , OR Management) in the planning phases of such activities. For general discussion and guidance on MDA in moderate to high transmission settings see Other Chemoprevention Approaches chapter ('*MDA*' sections) for more detail.

Interventions in the final phase of elimination are categorized as mass (all in a defined geographic area), targeted (individuals at increased risk of malaria) or reactive (individuals who share the same risk as a confirmed malaria case). WHO generally recommends **against** testing and treatment approaches which include Mass testing and treatment (MTaT), Targeted Testing and Treatment (TTaT), and testing and treating at points of entry to reduce importation of malaria. It does recommend **for** malaria testing and treatment of organized or identifiable groups arriving or returning from malaria-endemic areas. WHO conditionally recommends with very low certainty evidence targeted drug administration which is a form of chemoprevention involving the provision of a full therapeutic course of an antimalarial medicine to individuals at increased risk of malaria infection compared to the general population e.g., IPT in forest goers. In areas approaching elimination or post-elimination settings preventing re-establishment of

transmission, reactive drug administration whereby antimalarial medicine are given to all people residing with or near a confirmed malaria case and all people who share the same risk of infection (e.g. co-travellers and co-workers) and reactive case detection and treatment whereby all people residing with or near a confirmed malaria case and all people who share the same risk of infection (e.g. co-travellers and co-workers) can be tested for malaria and treated if positive are recommended **for** to prevent or reduce malaria transmission. Any country teams considering any of the newly recommended interventions except reactive case detection and treatment should consult with the PMI Headquarters Elimination Technical and Case Management Teams in advance of any consideration of MOP support as further evidence generation might be warranted.

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 3-5 years, as appropriate, to ensure that coverage of these critical interventions does not wane. In countries with high heterogeneity of transmission, sampling frames will need to be adjusted to ensure that surveys sample areas with malaria transmission risk.

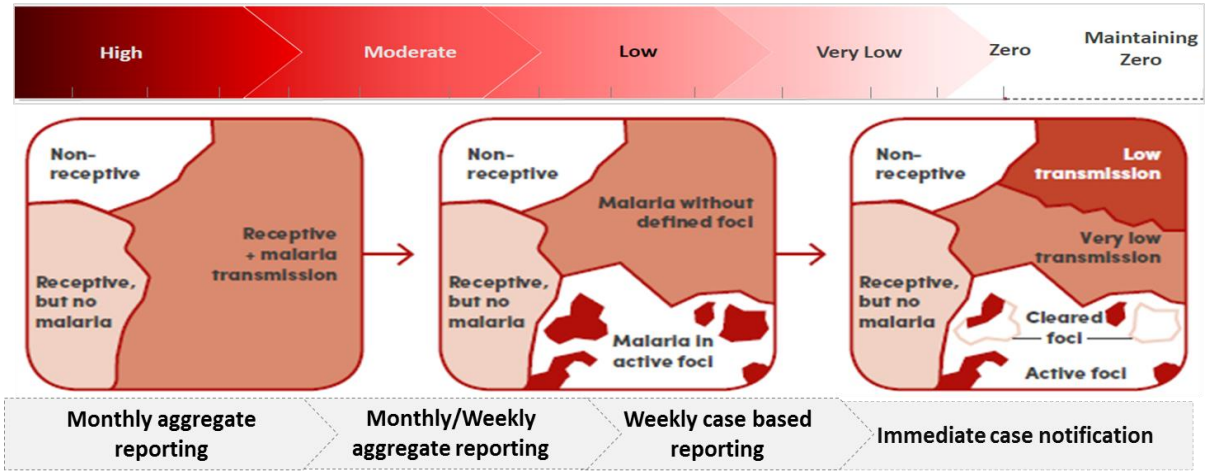
Although population surveys may still be needed in an elimination setting to monitor coverage of interventions, they become less useful for measuring morbidity. PMI has historically used national household surveys (e.g., MIS) to collect data on anemia and parasitemia, and DHS to track all-cause child 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 estimates in children under five years of age are <3%, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued. Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains significantly greater than 3% in other regions. PMI should bear less of the financial and logistic burden of organizing the DHS surveys in elimination settings. **Countries transitioning to elimination should increasingly use longitudinal health facility- and community-based surveillance data 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 increasingly important to target interventions. In high-transmission settings, most national malaria risk maps are derived from a combination of parasite prevalence data from household surveys, routine health information systems, and data from various other sources incorporating rainfall, temperature, topography, 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 NMPs to make strategic decisions regarding the deployment of various interventions, and to monitor progress towards elimination. (See section on stratification above).

Figure 17. Increasing spatial heterogeneity and frequency of malaria surveillance reporting as transmission decrease



Surveillance system requirements for elimination

1. **Implementation of a national system to collect facility- and community-based data on confirmed malaria cases 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 facilitate rapid response to prevent outbreaks and/or epidemics. A comprehensive surveillance system will need to incorporate data from all sectors, including public, private, non-governmental organizations, military, etc. Use of digital tools may facilitate collecting and

reporting data in this way (see Digital Community Health section of CHT guidance and Strengthening Community-Level Data Systems section of S&I 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 foci of transmission, to allow for targeted malaria control efforts. The investigation of a locally-infected index case and subsequent response measures could include testing and treatment of family members, co-travellers, and close neighbors. Geolocation is beneficial to identify areas of ongoing transmission and allow cross-referencing of control activities in the area to target additional efforts.

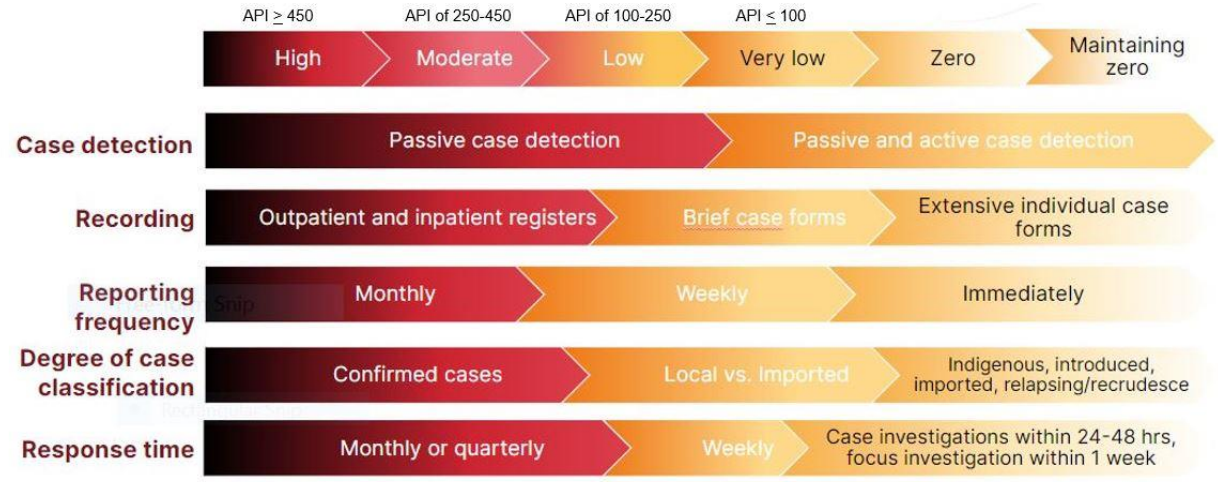
3. **Building disease surveillance and response capacity**: Strengthening disease surveillance capacity should be supported in all PMI focus countries. In elimination settings, the capacity of local health authorities to rapidly identify, investigate, and respond to outbreaks is critical. In such settings, 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, surveillance systems exist which detect, record, report, and respond to malaria cases at varying frequencies. Figure 18 highlights surveillance characteristics along the WHO transmission continuum.

Figure 18. Key surveillance characteristics along the transmission continuum[265]



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, while keeping in mind the transmission burden. The following points should help in making decisions on surveillance support.

- Surveillance system structures have different attributes and functionalities that impact their utility for guiding elimination activities. Health facility-based routine information systems (HMIS) and Integrated Disease Surveillance and Response [IDSR]—for a more general description of these systems see the S&I chapter) 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 alerts (weekly or even daily if necessary) though may lack the higher-resolution data needed for individual case investigation and response. IDSR systems could be used in outbreak detection and monitoring interventions in a timelier manner. Any considerations of support for parallel systems should be discussed with the PMI Headquarters S&I 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 a national malaria program 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, the MOH must coordinate data access to appropriate, timely data sources for the NMPs.
- 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

[265] This graphic is from the surveillance module of the WHO Malaria Elimination Course (2022) https://openwho.org/courses/malaria-elimination. WHO's API thresholds have been added to assist with interpretation.

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 and used, 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 smart-phone based reporting and response system. These can be used to collect patient-specific information and direct surveillance officer investigations of newly diagnosed cases and case clusters. Officers can record exact response activities in real time and either transmit to the central surveillance system or upload when connectivity is available. These technologies can also facilitate geo-location of the cases through built-in GPS functions, but require a functional data network.

A landscaping of available mobile technologies and a roadmap for mobile solutions for malaria elimination surveillance systems was commissioned by the Bill & Melinda Gates Foundation and is available at http://vitalwave.com/case-study/mobile-solutions-for-malaria-elimination-surveillance-systems/.

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

Please refer to the S&I chapter for general guidance on PMI supported activities for routine health information systems. The following are low burden approaches to that can be supported through PMI funding where appropriate:

- **Malaria mortality surveillance**: As stated in the **S&I chapter,** monitoring changes in malaria-specific mortality via passive surveillance alone is a challenge for malaria control programs. As programs approach elimination, accounting for deaths and confirming malaria infection will improve as all malaria cases are diagnostically confirmed and health information systems are strengthened. Generally, malaria mortality data from routine surveillance will become increasingly accurate and reliable. Furthermore, malaria deaths should become increasingly rare in elimination settings.

- **Active surveillance**: Active surveillance includes efforts to seek out additional cases of a specific disease and can take several forms. It can include community health workers or health workers visiting villages and going door to door looking for people with signs and symptoms of malaria, or testing all residents regardless of symptoms. Active surveillance is very resource- and time-intensive and is generally not considered until countries have a strong passive surveillance system and reach the elimination phase, when cases are few and health system capacity and resources allow. Mass testing and treating regardless of symptoms is not recommended by WHO. Active surveillance can be used in the elimination setting in several ways:
  - In areas approaching elimination or post-elimination settings preventing re-establishment of transmission, WHO conditionally recommends testing and treating organized or identifiable groups arriving or returning from malaria-endemic areas soon after entry to reduce importation of malaria.
  - Border screening or routine malaria testing and treatment of people arriving at points of entry (land, sea or air) to reduce importation is not recommended.

  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 reactive drug administration are being evaluated as a strategy to reduce and interrupt transmission. In addition, it is strongly advised that if reactive drug administration activities are being considered, this should be done in consultation with the PMI Elimination Technical Team

and 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. 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"[266] 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.

  WHO conditionally recommends for reactive case detection and treatment based on very low certainty evidence **only in areas approaching elimination or post-elimination**. 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. 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)**: 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 and WHO recommends **for** this intervention in settings approaching elimination or post-elimination. In areas approaching elimination or post-

[266] 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, countries can consider the implementation of RDA keeping in mind the need for ongoing evidence generation as WHO's recommendation was based on very limited data.

PMI Elimination Indicators

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 and classified
- National stratification updated in the past year
- National Strategic Plan and Surveillance, Monitoring & Evaluation 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 (SBC) in Elimination Settings

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. In addition to communities, SBC activities should also target facility and community-based health providers and other key stakeholders relevant to malaria elimination. With reduced incidence of malaria, health providers may not suspect malaria, and case definitions and treatment protocols may not be remembered as clearly thus, provider behavior change activities may be needed (refer to the SBC Chapter for more information on SBC in Service Delivery).

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 1 featured in the SBC Section provides an overview of behavioral considerations across the transmission continuum and are described in more detail in the SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low, and Zero Malaria Transmission report. Please refer to the SBC Chapter for more detailed descriptions of the approaches supported by PMI across all transmission settings).

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 NMP 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.

SBC for Vector control

Two of PMI's main interventions – insecticide-treated mosquito nets (ITNs) and indoor residual spraying (IRS) – are aimed at controlling mosquito populations and are especially important in sub-Saharan Africa where nocturnal indoor-biting and resting behaviors are common. While these interventions are highly effective, the gains may be quickly reversed if net use or IRS acceptance falls. As such, the transient adoption of a behavior is not enough, particularly in an elimination setting; consistent use of ITNs and acceptance of IRS must be maintained at high levels.

While behavior maintenance for ITN use and acceptance of IRS is important in areas transitioning to low, very low and zero transmission, additional considerations should be made. For example, establishing or reinforcing net use in fixed or sedentary communities may function differently than in high risk communities such as those that live in makeshift dwellings and/or sleep outside for months at a time, those with outdoor occupations (e.g., forest goers, security guards, agricultural workers), 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 ITNs, topical repellents are only effective when used. However, while ITN 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 ITNs is feasible would represent an inefficient use of PMI resources.

SBC for Case management

A key component of SBC for malaria case management is increasing treatment seeking behaviors especially through the public sector. In all transmission settings, SBC for case management at the community level should focus on establishing trust in the malaria test result and raising awareness of the broad spectrum of fever causes. It is equally important that SBC targeted at service providers focus on increased awareness of the broad spectrum of fever causes, emphasize adherence to national case management guidelines (for diagnosis and treatment) and improved communication for patients who do not receive treatment for malaria when presented with a negative RDT.

SBC for Malaria in pregnancy

At the community level, SBC should encourage consistent ITN use, ANC attendance, prompt testing and treatment seeking for fever, and promote the uptake of IPTp, when appropriate. Activities that target service providers should continue to encourage provider adherence to national guidelines for IPTp dosing (timing and frequency) and malaria case management.

SBC for Surveillance, monitoring, and evaluation

As countries shift to lower transmission and improve SM&E activities to capture robust case-based 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[267], for indicators that can be adapted for elimination settings.

To measure malaria-related behaviors and the internal and social factors associated with those behaviors, the PMI SBC Technical Team recommends the implementation of the Malaria Behavior Survey (MBS). The tool is a theory-driven, cross-sectional household survey that will help to inform the design, implementation, and evaluation of SBC interventions. The tool has been adapted for implementation in low-transmission settings through coordinated efforts between the SBC and Elimination Technical Teams and is available at malariabehaviorsurvey.org. . Please see the SBC Chapter for more detailed information and contact your HQ SBC Team POC if you are interested in learning more for implementation in your country

While household surveys may still be used to measure behaviors of fixed populations (geographically and demographically), additional considerations for SBC SM&E activities include shifting to examining mobility as a system (e.g., monitoring human movement) and determining what effect the direction of that movement will have on malaria transmission. The Greater Mekong Sub-Region has implemented SBC interventions targeted towards mobile populations that have included net lending programs and interpersonal communication with travelers along known travel routes. Countries with mobile populations may wish to build off the lessons learned from experiences in the Greater Mekong Sub-Region. Please see your Headquarters country support for additional information about other PMI countries conducting research, SM&E and SBC efforts focused on mobile and migrant worker populations.

[267] RBM Partnership to End Malaria. 2017. Malaria Social and Behavior Change Communication Indicator Reference Guide: Second Edition. Venier, Switzerland: RBM

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[268] guidance, re-introduction of malaria is defined as the occurrence of introduced cases (i.e., cases of first-generation local transmission that are epidemiologically linked to a confirmed imported case) in a country or area where the disease had previously been eliminated. Re-establishment of transmission is defined as the occurrence of 3 or more indigenous cases of malaria of the same species per year in the same focus for 3 consecutive years. Countries that are approaching elimination should develop a comprehensive program for prevention of reintroduction and/or re-establishment 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 re-introduction of malaria transmission; 3) immediate action in the event of renewed local malaria transmission; and 4) determination of the risk of malaria reintroduction on the basis of assessment and regular monitoring of receptivity and importation risk of the area; in addition to implementation of activities as appropriate to reduce receptivity and importation risk. This includes SBC activities in addition to personal protection and prevention tools and measures, as appropriate.

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 those detected by the private sector) must be reported and investigated in a timely manner, and information compiled in a national register of malaria foci. Diagnostic capacity and quality of laboratory services should be maintained through consistent and integrated training and retraining of key personnel. Attention should also be paid to ensure adequate community awareness and vigilance about inevitable importation of malaria parasites. A POR strategy should also include identification of adequate resources (financial, human, etc) for sustainability.

In an increasingly mobile world, malaria imported by visitors (both foreign and domestic) and migrant workers carries some risk of re-establishment of local transmission of malaria in areas where *Anopheles* mosquitoes are still present and conditions for spread are favorable. Thus, receptivity and importation risk 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

[268] Regional Framework for Prevention of Malaria Reintroduction and Certification of Malaria Elimination (2014-2020), Regional Office for Europe

should be maintained. Importation risk refers to the probability of importation of malaria parasites into a country or a particular area.

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 human malaria over the preceding three years while having a system in place to prevent re-establishment of indigenous transmission. 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, at least until malaria is eradicated globally. However, it is important to maintain capacities to detect and respond to malaria cases, even after a country receives certification of malaria elimination. In fact, the presence of these capacities (in the form of a prevention of re-establishment program) is one of the two requirements for certification.

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 could prepare and begin laying the groundwork for certification of national malaria elimination by starting verification efforts at subnational levels. WHO does not provide specific guidance for subnational verification 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 and/or re-establishment of local malaria transmission.

Preparation for certification of elimination needs to start before a country has reached zero local cases. Documentation that is required for certification should cover about 5 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.

Resources

- WHO Malaria Elimination Course (2022)
- **Malaria eradication: benefits, future scenarios, and feasibility. Executive summary, WHO Strategic Advisory Group on Malaria Eradication (WHO, 2019)**
- **Malaria surveillance, monitoring & evaluation: a reference manual (WHO, 2018)**
- **A framework for malaria elimination (WHO, 2017)**
- **The *Lancet* Commission on malaria eradication Comment (2019)**
- The Investment Case for Malaria Elimination in Thailand: A Cost–Benefit Analysis (AJTMH, 2019) **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6553898/**
- Social and behavior change considerations for areas transitioning from high and moderate to low, very low and zero malaria transmission https://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf
- A Foci Cohort Analysis to Monitor Successful and Persistent Foci under Thailand's Malaria Elimination Strategy (Malaria Journal, 2021) https://malariajournal.biomedcentral.com/articles/10.1186/s12936-021-03648-8
- Malaria elimination using the 1-3-7 approach: lessons from Sampov Loun, Cambodia (BMC Public Health, 2020) **https://pubmed.ncbi.nlm.nih.gov/32321475/**
- Policy brief on single-dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria, January 2015: http://www.who.int/malaria/publications/atoz/who_htm_gmp_2015.1.pdf

OPERATIONAL RESEARCH AND PROGRAM EVALUATION

New/Key Messages

Funding for Operational Research (OR) activities: OR activities can either be funded through MOP, core or a combination of the two sources. External resources (e.g. from the Bill and Melinda Gates Foundation) can be leveraged for both MOP or core-funded studies.

Central OR Mechanism: PMI Insights is a central OR and program evaluation (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 is the default mechanism for **core-funded** OR/PE and can also support MOP-funded activities spanning full implementation to targeted technical assistance e.g., study design, protocol development, modeling, statistical and laboratory support.

MOP-funded OR/PE: All proposed OR and PE topics should be captured under the OR/PE heading in both the narrative and Table 2 and at minimum include a clear question, proposed study design, study implications, allocated budget, and mechanism. 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 may fall outside the core-funded OR/PE prioritization process. Requests for concept note submission will be sent out annually (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. **Only MOP-funded OR** studies will require protocol review by the OR Committee prior to submission to relevant ethical review boards.

Core-funded OR/PE: All core-funded OR priorities are aligned with the final Global OR Prioritization Agenda which generated 33 ranked, country-driven OR/PE priority topics. Of these topics, PMI will incorporate the additional inputs (e.g. PMI strategic focus areas, annual MOP submissions, interagency technical team priorities, and donor/stakeholder consultations with the Bill and Melinda Gates Foundation (BMGF), Global Fund to Fight AIDS, Tuberculosis, and Malaria (GF) and WHO to inform core OR/PE investments. Concept notes and subsequent protocols for all core-funded PE and OR need to be submitted to the OR Management team for OR Committee review and approval.

PMI OR/PE Portfolio: All PMI-funded completed and on-going OR studies are searchable through an

external website hosted by MesaTrack. The OR Management team will solicit 6-monthly updates for all on-going OR studies.

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 over 50% by FY 2030. Each core-funded study implemented under PMI Insights 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 national malaria program (NMP) and in-country research institution involvement and potential policy or programmatic impact of the study results.

Distinguishing activities that do not require OR Committee Review: PMI undertakes many monitoring and evaluation (M&E) activities which include routine surveillance and M&E/PE approaches that are repeated across countries and are standardized (e.g., TES, MIS, DHS, entomological assessments, ITN durability monitoring, Malaria Behavior Surveys, End User Verification Surveys, health facility 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. Furthermore, specific contexts of larviciding for *Anopheles stephensi* response or the deployment of topical repellents in the context of forest goers in the Mekong do not require OR Committee review. 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 routine health management information system data only to evaluate the impact of NMP's distribution of PBO nets would not require OR Committee review. Please consult the OR Management Team if there are any questions on whether the study requires OR Committee review.

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. For routine surveillance and survey activities, CDC has two existing umbrella protocols which may apply. Please refer to section "CDC PMI Umbrella protocols" for further details.

Introduction

Over the past 15 years, PMI has strived to generate evidence through both operational research (OR) and program evaluation (PE). Both PE, aimed at improving ongoing program activities in the local setting, and OR, to generate generalizable information, have been critical in improving the successful implementation of PMI malaria control and elimination strategies and in achieving PMI's goals (See Table 1 in the Distinguishing Operational Research and Program Evaluation 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 as well as external resources.

The guidance below focuses on objectives and priorities, guiding principles and processes for proposing PMI-funded OR/ PE for PMI country teams and headquarter's 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: 1) country-driven prioritization agenda will inform core investments; 2) studies should partner with local research institutions whenever possible to lead the design, development, implementation, and publication; 3) 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 25% by FY2025 and 50% by FY 2030 aligning with USAID's goals 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)
- Assess effectiveness and feasibility of new interventions and approaches that offer the potential for use by PMI-supported programs in the near future
- 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
- Assist in optimizing program efficiency by addressing bottlenecks in malaria prevention and

control

Funding Sources and Channels/Mechanisms for PMI Operational Research and Program Evaluation

Funding for PMI OR/PE activities mainly 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 NMPs and local partners, and are often 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**: Country-led OR/PE prioritization topics supported by PMI and funded centrally with PMI core funding generally address broader issues applicable across many PMI countries. They may involve two or more PMI countries and/or require several years to complete. The amount of core funding available for priority OR/PE activities may vary from year to year depending on several factors including the overall total PMI budget and other PMI core budget priorities.

OR may be conducted through a variety of mechanisms such as those listed below. If you have interest in developing OR/PE, you are encouraged to contact the OR Management team so that they may assist in identifying the most appropriate mechanism as early as possible.

Options include:

1. PMI's 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 as prime recipients or through subcontracts;
3. Research collaboration involving CDC and/or USAID headquarters technical staff and a USAID country bilateral or central implementing partner mechanism.
4. Use of the CDC Interagency Agreement (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 (Frank Burkybile) with questions regarding project scope and timeline. PMI Insights is 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. **It is important to note that core-funded PMI Insights is not a replacement of MOP-funded OR/PE; countries are strongly encouraged to consider MOP funds to address country specific OR/PE questions.**

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/NMP/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/NMP/host country government institutions (G2G) through CDC with USAID appropriated funding (PMI or all other types of funding) is prohibited by USAID agency-level policy restrictions. (See PMI Policy, 'CDC Interagency Agreement' section.)

It is expected that CDC should advise the Malaria Coordinator on priorities for operation and implementation research and be a key implementer of PMI-supported OR, as specified in the Lantos-Hyde Act. 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.

Important to note: Regardless of the funding mechanism used to conduct the OR/PE study, if there is a delay of concept note/protocol development or a delay in the start of the implementation of activities within 12 months of funding availability please inform the OR management team to discuss the nature of the delays and to obtain any necessary approvals.

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 potential donors like BMGF and GF based on a signed Memorandum of Understanding as part of the regular OR/PE donor collaboration. 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 (MOP and/or core) and the specific cost(s) associated with these components as well as summarize the co-funding from other sources for the study, with the concept notes clarifying the mechanism through which each source of funding will flow. Even if PMI contributions are limited to staff time or provision of commodities, these are considered PMI support, and a concept note outlining these contributions in the context of the full study must be submitted.

PMI OR Priority Setting Process

The OR/PE priority setting process aims to generate a strategically narrow, focused set of scientific and OR/PE priority questions for core-funding to support the PMI Strategy 2021–2026. In 2020, PMI Insights began 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 FY2022 core-funded priorities and beyond, PMI will align with the **Global OR Prioritization Agenda** incorporating the following inputs: NMP priorities, annual MOP submissions, interagency technical team input, and donor consultations with the Bill and Melinda Gates Foundation (BMGF), the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GF), and other relevant organizations. The OR Management team will lead this process and will work with the PMI Front Office to gain approval of the U.S. Global Malaria Coordinator on updates to OR/PE priorities.

The OR/PE prioritization process applies to **only** 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 should be

included in the country MOP or reprogramming request submission and captured under the Monitoring, Evaluation, and Research cost category in Table 2. Approval of a MOP that includes OR/PE funding does not constitute approval of the study and is only the first step. Following funding allocation, concept notes and protocols (if OR) still need to be submitted for technical review by the OR Committee during the annual request for MOP-funded OR/PE concept note review (Q4) in order to be considered approved.

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 should respond to country-specific priorities and needs, while core-funded OR may address broader issues that are relevant across PMI's programs. Due to this focus, core-funded OR may be conducted across multiple countries and address fundamental questions to achieve optimal impact from proven or promising interventions.

Guiding principles for country-led (MOP-funded) research:

Although MOP funds can support either OR or PE, country resources are often oriented towards PE and generating local data with the aim of improving:

1. Coverage and quality of interventions
2. Efficiency in intervention delivery and reaching target populations including those previously unreached

In the MOP or Reprogramming 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.

Please reach out to the OR Management to explore opportunities to leverage core-funded activities as well as multi-country coordination.

Guiding principles for core-funded research:

Core-funded study ideas will focus on:

1. Further reducing malaria transmission, disease burden and/or mortality;
2. Testing effectiveness of new interventions and strategies or combinations thereof; and
3. Exploring new metrics and mechanisms to assess the impact of interventions.

General considerations for both MOP- and core-funded OR/PE priority submissions include:

- Is the idea strategically important to PMI (i.e., 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, i.e., was it identified in the country-driven research prioritization agenda?
- 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?
- The estimated time from study conception to likely time of intervention implementation, result dissemination, and/or expected policy change.

A list of all PMI- and BMGF-funded OR/PE projects can be found in the MESATrack database. Mapping of donor investments against the 33 country-driven priority topics has been conducted by PMI Insights and will be made publicly available.

Study Review and Approval Process

MOP-Funded OR/PE

Concept notes are required to be submitted to the OR management team for both MOP-funded OR and PE studies with the exception of routine standard surveys or monitoring activities (e.g., TES, MIS, DHS, entomological assessment tools, ITN durability monitoring, Malaria Behavior Surveys, health facility surveys, end use verification surveys, project midline and end-line evaluations, etc.) **[see below for details].**

Review of MOP-funded OR/PE concept note

The OR Management team will solicit concept notes (using the template found in the OR Technical Resources folder in the PMI G-Drive) for MOP-funded OR or PE ideas approved in the MOP review or reprogramming process from country teams annually (Q4). **Concept notes are required for both**

MOP-funded OR and PE studies. Please reach out to the OR Management team to discuss the timing of a concept note submitted outside of the annual solicit. 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 review period (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 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 technical review. Complete concept notes will be sent to the OR Committee (or designee) for technical review and feedback and a response returned to the study point of contact (POC) within **two to three weeks** of the submission due date. Please note that a concept note can be considered complete even if a mechanism for implementation is considered TBD at the time of submission.

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.

The review will clearly note the outcome and further action needed, if any.

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, not already addressed, 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 with an outcome of "approved" or "resubmit."

Protocol review of MOP-funded PE studies

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.

Core-Funded OR/PE

Upon identification of core-funded OR/PE topics, focal points from the OR Management team and the OR Committee will be assigned to each project to ensure early incorporation of input and ensure submission of high-quality, well-aligned concept notes.

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.

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.

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. Operational research 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 monitoring and evaluation (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, ITN durability monitoring, Malaria Behavior Surveys, health facility surveys, end use verification 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 monitoring and evaluation 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 routine health management information system data only to evaluate the impact of NMP's distribution of PBO nets would not require OR Committee review.

There are additional exceptions noted in the respective technical sections of this guidance where OR Committee review of a concept note is not required:

1. Larviciding in response to *Anopheles stephensi* [Please refer to the XX section]
2. Use of topical repellents in the context of malaria elimination in the Greater Mekong Subregion. Please refer to the Elimination chapter for further details and additional information for study design considerations in very low transmission context.

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.

Table 12. 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 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 two non-research umbrella protocols to help encompass these activities reducing the burden of submitting each activity separately. Please work with CDC DPDM Human Subjects and Annett Cotte as the point of contact on the OR Management Team to ensure all needed prior review is appropriately sought.

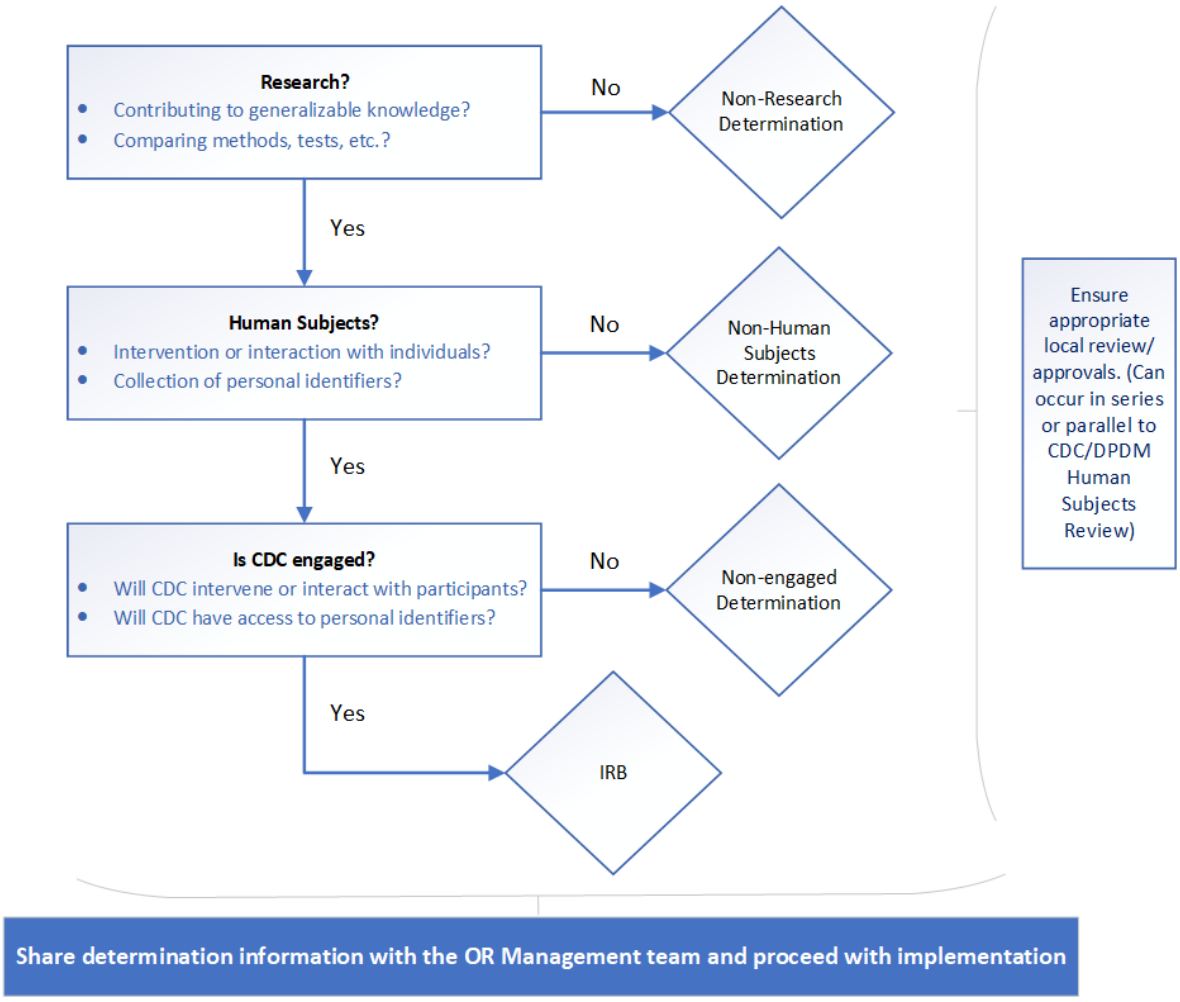
Research Determination Process

Research determination is the systematic evaluation of whether a proposed activity constitutes research and involves human subjects, and is undertaken by an independent ethical review board/unit. There is an ethical and legal obligation to ensure that individuals are protected in all public health research activities. As much as possible, PMI-funded studies should streamline this review to rely on a single Institutional

Review Board (IRB). All PMI-funded OR and PE are required to undergo appropriate human subjects review by a relevant IRB. In most cases, CDC staff person(s) will be involved in the OR/PE projects requiring that this review include CDC which has an established Federal-wide Assurance (FWA) and IRB for ethical review. USAID does not maintain its own IRB and relies on implementing partners to follow appropriate regulations and obtain the necessary approvals to ensure the protection of human subjects.[269] 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 19 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 research by an ethical review board will need to submit their full protocol for review by the OR Committee even if they were initially submitted as MOP-funded PE.

Figure 19. Guiding questions for CDC's Human Subjects Review

[269] Please refer to ADS chapter 200 "Protection of Human Subjects in Research Supported by USAID" for more information: https://www.usaid.gov/sites/default/files/documents/1864/200mbe.pdf



CDC PMI *Umbrella protocols (Relevant for CDC staff)*

CDC's Malaria Branch has developed and received human subjects approval for two umbrella protocols for PMI activities specifically covering 1. Routine surveillance ("Use of Routinely Collected Health Management Information System Data and other Routinely Collected Program Data in Support of the President's Malaria Initiative (PMI; Project ID # 0900f3eb819cbc38) and 2. Routine surveys ("Routine Surveys for Monitoring the President's Malaria Initiative (PMI); Project ID clearance # 0900f3eb819cbd87). The routine surveillance umbrella protocol is designed to cover use of routinely collected surveillance and program data such as analysis of routine HMIS data, entomological monitoring data, etc. Activities covered under the routine survey umbrella protocol include standard household surveys, end use verification surveys, ITN coverage surveys etc. Activities that fall under either one of the two umbrella protocols do not need to be submitted for ethical review at CDC however they are required to be tracked. Without tracking, these activities would require a separate

human subjects determination. An annual country specific review meeting with the Associate Director of Science at the Division of Parasitic Disease and Malaria is required to review and document all activities that would fall under these umbrella protocols. The Available Malaria Surveillance Sources table from the MOP document is used for these tracking purposes. For questions about the umbrella protocols please contact Annett Cotte or Jimee Hwang.

Study Budget

The OR Committee review of concept notes covers technical and budgetary aspects. A well-thought out budget (using the template located in the OR Technical Resources folder in the PMI G-Drive) is therefore required prior to submitting the concept note to the OR Management team. The expectation is that there should not be a significant difference between the budget proposed in the concept note and the protocol budget. A significant difference is defined as a difference greater than 10% between the original concept note budget and final protocol budget. If a protocol budget is greater than 10% of the budget proposed in the concept note, the study POC must submit a justification (less than half a page) to the OR Management team along with the protocol. Efforts must be made to develop a detailed budget at the concept note stage since study budgets are required for OR Management team and OR Committee review.

Any changes in the technical approach (including research questions/objectives, design, study sites, and methodology) or the budget (exceeding 10%) of **approved protocols/ongoing studies** requires review and approval by the PMI Front Office through reprogramming of MOP-funded studies or action memos for core-funded studies and the OR Committee.

Commodities for OR

For OR studies that require commodities (including RDTs, ACTs, ITNs, etc.), it is recommended that orders are placed through the PMI supply chain project so that quality of the commodities can be assured. Once a concept note is approved, the PMI point of contact(s) must inform the Supply Chain Liaison on the OR Committee (Rima Shretta) 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. **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 mechanism.** For core-funded OR commodity needs, the estimated funding for commodities outlined in the study budget will be directed to the centrally-managed malaria commodities procurement project. For MOP-funded OR commodity needs, country teams should specify at least two mechanisms for the OR study – the mechanism implementing the research and the PMI centrally-managed malaria commodities procurement project with the estimated commodity costs directed to the commodity procurement

mechanism. Please consult the commodity ordering lead time table available in the Supply Chain section for procurement lead times and plan accordingly.

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 in-country and/or headquarters staff time to the development, implementation, and/or analysis of the study. In such scenarios (e.g., the recent CDC International Task Force funded COVID-19 proposals where PMI support is limited to staff time and commodities), the study concept note and/ or protocol will need to be submitted to the OR Management team 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, and Agency leads) is responsible for providing overall annual budget guidance and approval of core-funded OR/PE priorities.

Please refer to Figure 20 below for the OR Management Team and the OR Committee Member composition.
Responsibilities of the OR Management team include:

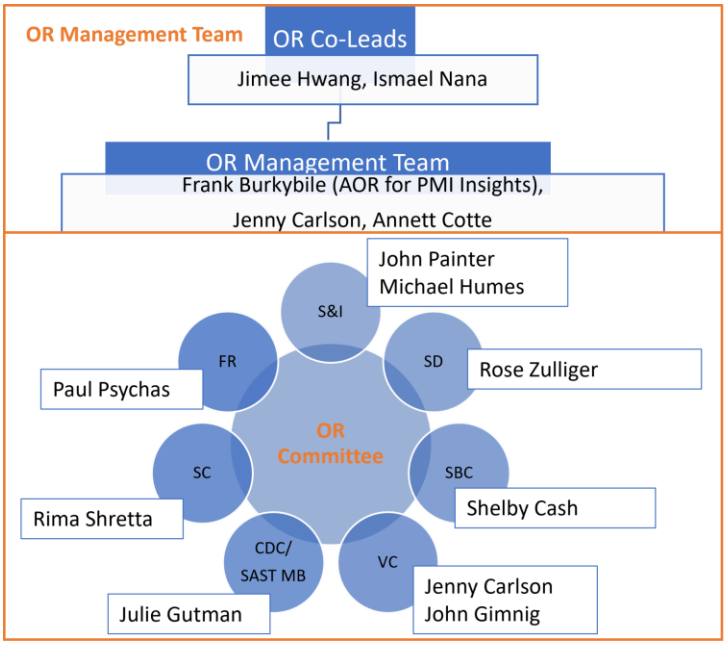
- Coordinate with PMI Front Office Team on OR priorities
- Coordinate with GF and BMGF on Workstream OR
- Manage the PMI Insights OR central mechanism
- Manage OR communications to PMI HQ and Country teams
- Manage concept notes, track proposals/protocols/reports/budgets, track semi-annual study progress 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 determine if any ideas or issues should be considered for addition to the prioritized list.

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.

Figure 20. OR Management Team and OR Committee member composition



OR- operational research, AOR- agreement officer representative, S&I- surveillance& informatics, SD- service delivery, SBC- social behavior change, VC- vector control, CDC/SAST MB- CDC/Strategic Applied Science Team Malaria Branch, SC- supply chain, FR- field representative

Dissemination

Most PMI-funded completed and on-going 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 NMP/other implementers.

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 the OR Technical Resources folder in the PMI G-Drive. 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, coordinate among studies, and for internal or external updates including the PMI annual report, Research Reports to Congress, the PMI.gov website, and MesaTrack. A completed study questionnaire found in the OR Technical Resources folder in the PMI G-Drive, 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 strengthened 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 headquarters or country staff can submit a manuscript or abstract for clearance (i.e., manuscripts of PMI-supported partners must be submitted by the PMI headquarters or country point-of-contact for that project). If there are CDC co-authors, please ensure that the document has been fully cleared by CDC before submitting for PMI Policy Clearance.

Authorship of Publications Resulting from OR/PE Activities

PMI strongly encourages staff publication of work and supporting NMP and local researchers to lead publications. 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 critical. 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 operational research (http://www.who.int/bulletin/volumes/94/1/15-167585/en/)
- Gather for studies that calculate health estimates (http://gather-statement.org/gather-statement/)

Peer-reviewed Publication, Authorship, 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.

To address gaps in equitable authorship, some journals, notably PLOS Medicine, now require that local researchers be first or last authors of publications based on global research.[270]

In addition, to facilitate compliance with the U.S. Government'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, USA
- 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, U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA
- For CDC field staff: U.S. President's Malaria Initiative, U.S. Centers for Disease Control and Prevention, City and Country of posting
- For Implementing Partner staff: Project Name, Institution, City and Country (example: PMI Insights, PATH, Seattle, WA, USA)

[270] Odeny B, Bosurgi R (2022) Time to end parachute science. PLoS Med 19(9): e1004099. https://doi.org/10.1371/journal.pmed.1004099

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 U.S. 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 U.S. Centers for Disease Control and Prevention or the U.S. Agency for International Development."

Table 13. Annual OR Timeline

Quarter (Q)	Q1	Q2	Q3	Q4
Prioritization				
Review of Global OR Prioritization Agenda or Refresh, if available	X			
MOP Submissions		X		
Technical Team engagement, OR Management and Committee Review, as needed			X	
Front Office Review and Approval, as needed				X
Implementation				
MOP-funded OR/PE Concept Note Submission				X
Semi-annual OR updates	X		X	

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 health systems strengthening. PMI investments in systems that deliver health services at facility and community level, that ensure stable supplies of quality assured commodities, and that enable monitoring and evaluation of progress and impact of interventions are critically necessary 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 NMPs and local government staff; (3) Peace Corps; and (4) the Field Epidemiology Training Program.

Introduction

Stronger health systems are necessary to extend access to health services to the populations most at risk from malaria to deliver sustainable improvements in health outcomes, and ultimately to contribute to countries' economic growth. Investing locally and strengthening health systems are not only core areas of focus in the PMI Strategy 2021–2026, but have been guiding principles for PMI since its launch. It is an essential 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) to ensure the resilience of health systems and advance frontline health services. 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 prevention and control.

PMI's support for HSS is aligned with **USAID's Vision for Health Systems Strengthening 2030**, which emphasizes that health systems strengthening is critical to the achievement of USAID's goals of Preventing Maternal and Child Deaths, Controlling the HIV/AIDS Epidemic, and Combating Infectious Disease. The Vision focuses on health systems outcomes, including desired intermediate outcomes of equity, quality, and resource optimization that lead to positive health outcomes in the countries USAID partners with. The Vision also stresses the need to consider the "how" and "why" of the types of activities chosen, noting that locally driven, integrated activities that address multiple functions of the health system simultaneously can help ensure sustainability while advancing the objectives of equity, quality, and resource optimization.

Most, if not all, PMI-supported activities – whether intervention-specific or cross-cutting – contribute to strengthening health systems. Examples of the types of activities that contribute to health systems strengthening include:

- Investments in country leadership and governance structures and capacity (e.g., technical and management capacity strengthening at all levels, including trainings and courses);
- Contributions to the design of countries' national health insurance strategies and/or universal health care programs in order to ensure that they include appropriate coverage of malaria and other essential services and support structures to ensure the provision and improve the quality of those services;
- Support for health worker training, supervision, mentoring, and capacity strengthening for public and private sector providers of integrated services;
- Support for community and primary health care workers and community and primary health care programs providing integrated services;
- Quantification of gaps and needs in service delivery and human resources for health to provide essential services and reach populations at risk;
- Social and behavior change activities, including service communication, aimed at positively influencing care-seeking, the quality of care, and the adoption of desired health behaviors by addressing internal, environmental, and/or social factors;
- Support for national implementation of electronic logistics information systems (eLMIS) to improve data availability and data-driven decision-making for the management of commodities;
- Requiring suppliers comply with global standards to enhance end-to-end traceability of products, and strengthening in-country systems to use the data;

- Support for pharmaceutical management systems (including strengthening warehousing and distribution, forecasting and supply planning, and outsourcing and performance management of private logistics providers) ;
- Strengthening national regulatory and product registration systems;
- Strengthening the quality management systems of local manufacturers of malaria and other essential commodities to meet global quality standards (e.g. WHO prequalification); and
- Development, use, and assessment of digital solutions to improve how essential services, including those for malaria prevention and treatment, are provided at the community level.

PMI programs should seek to support these types of activities, while also ensuring they are locally led and integrated across health areas, insofar as planned activities also contribute to malaria prevention and control outcomes. There are, however, some limitations on the types of activities that can be supported. 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)[271]. PMI can, however, 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 NMP or Ministry of Health to work as integral members of those 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 NMP.

Integration with Other Health Programs

Whenever possible, PMI looks for opportunities to integrate malaria activities with other USG-supported health and development programs in-country. USAID's Vision for Health Systems Strengthening 2030 and the *PMI Strategy 2021–2026* both clearly articulate the importance of integration. "The *PMI Strategy 2021-2026* states: "Where beneficial, integrate malaria activities with [other USG investments in] 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.

[271] For detailed guidance on how PMI may support paying community health workers, please see the Community Health Section of the guidance. Please note that PMI's payment of community health workers is not equivalent to hiring public sector staff.

It is expected that many health 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. To identify opportunities to integrate malaria activities with other USG-supported health and development programs in-country, PMI teams are strongly encouraged to liaise with colleagues working in other health areas in the country and engage regularly on topics with the potential for shared benefit, including surveillance and laboratory strengthening, social and behavior change, and supply chain strengthening. Designation of a PMI activity manager to lead this engagement is a best practice. In proposing integrated activities, PMI should ensure that:

- Funding sources other than just PMI are contributing to the proposed integrated activity and these sources are described within the MOP.
- For activities carried out by implementing partners with a mandate that extends beyond malaria:
    - The implementing partners for the integrated activities should have one or more staff members with expertise planning and implementing the malaria control interventions for which they are responsible;
    - Malaria-specific objectives and targets should be included in the monitoring and evaluation plan for the activity and within the partner's overall project scope of work and annual work plans;
    - The partner should be able to account for PMI funding and measure and report on PMI objectives and targets separately from other non-malaria activities; and
    - PMI staff should review and concur with annual work plans and actively 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.

For instance, global health security programming often 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, global health security 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 to insecticides used for

vector control. They may also contribute to strengthening community health systems and routine health information or disease reporting systems. Malaria vaccine introduction provides another example of where integration may be especially beneficial. As detailed in the SBC Section, PMI teams may choose to support SBC activities to facilitate demand generation for the malaria vaccine. Given that vaccine delivery is expected to take place using existing EPI platforms, integration of planned SBC activities with maternal and child health programming in areas where the malaria vaccine will be introduced will be critical.

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, health systems strengthening activity descriptions should clearly describe the intended contribution to malaria control and/or elimination efforts. Health systems strengthening activities should also 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 or elimination program strategy and goals, and if the financing goal is broader than malaria, malaria funding must be integrated with other funding streams.

Training and Capacity Strengthening of NMPs and Other Local Government Entities

Capacity strengthening activities with national malaria programs and other local government entities should be described in detail in relevant intervention sections of the MOP (i.e., training and on site supervision to strengthen diagnosis and treatment should be described in the case management section). Training activities for NMP and other government staff that do not appear within the technical intervention sections of the MOP 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 and elimination, 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 both other health areas and other donors and international organizations (e.g., Global Fund, World Bank, WHO, BMGF, etc.) also support 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 NMP or Ministry of Health 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 NMP.

Direct government-to-government (G2G) support to NMPs 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 Section for more information.

PMI supports and encourages NMP 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 NMP 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 NMP staff but instead should be a component of an activity aimed at further strengthening leadership and capacity of NMPs.

Peace Corps

Background

At the start of the COVID-19 pandemic, Peace Corps (PC) temporarily suspended all operations globally and evacuated all Peace Corps Volunteers (PCVs), returning them to their homes of record. Prior to this suspension, there were over 3,400 PCVs in Africa, and over 2,400 PCVs in PMI partner countries in Africa across sectors (health, education, agriculture, environment, youth, community economic development). PC was, therefore, well-positioned to assist in the collective efforts of the USG to reduce the burden of malaria in sub-Saharan Africa. As of October 2022, PC had re-opened programs in 30 countries, with only programs in two PMI partner countries yet to reopen (Ethiopia and Mozambique).

For the past decade, PMI has partnered with PC in the fight against malaria in countries in sub-Saharan Africa where PMI and PC each have a presence. Funding for this is provided through the USAID Small Project Assistance (SPA) interagency agreement between USAID and PC, which supplements the PC

appropriation. In countries where there is collaboration between PMI and PC, all activities must align with the national malaria strategy and be part of the malaria control and elimination effort led by the NMP. Consultations between staff from the PMI and PC should occur prior to beginning any collaboration to ensure that activities are complementary and technically sound. Collaboration between PMI and PC was underway in 15 countries prior to the onset of COVID-19.

Examples of activities supported by PCVs and PC Malaria Volunteers (MVs) include:

- Assisting with the organization and monitoring of ITN mass distribution campaigns at the district and community levels;
- Helping PMI implementing partners with malaria interventions, such as preparing communities for indoor residual spraying or organizing and assisting with training programs on community-based case management;
- Supporting SBC interventions (e.g. community dialogues, household visits, health center chats, school health clubs, etc.), 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 with partners; and
- Documenting and sharing operational and community-based best practices within and across countries.

There are three potential ways PMI can financially support a collaboration with PC through the MOP process: (1) funding for up to three PC MVs; (2) funding to support PCV-facilitated community-level malaria projects; and (3) funding for malaria training events for PCVs and PCV counterparts.

1. **Funding PC MVs**: PC MVs are experienced PCVs either serving a third year in their initial country of assignment, or PC Response Volunteers (PCRVs). Typically, PCRVs are volunteers who have already completed their initial two years of PC service and who have applied for another short-term assignment in the same or a different country. PCRV service may or may not be contiguous to the volunteer's initial PC service.

   PC MVs (whether PCVs or PCRVs that were PCVs and have a malaria scope) are expected to work closely with PMI in-country staff and the NMP as well as collaboratively with other malaria partners active in the country to support national malaria control and elimination efforts. PC MVs can also play a coordination and mobilization role for malaria activities carried out by other PCVs in the same country (including non-health sector PCVs).

PMI country teams may support up to 3 PC MVs by budgeting approximately $10,000 per PC MV per year. There are two potential mechanisms to support PC MVs: (a) the USAID Small Project Assistance (SPA) interagency agreement between USAID and PC 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-facilitated community-level malaria projects**: PMI can support PCV-facilitated community-level malaria projects (i.e. community dialogues, health center chats, school health clubs) through a small grants process, **budgeting a maximum of $10,000 per year** .

   The mechanism to support PCV-facilitated community-level malaria projects is the USAID Small Project Assistance (SPA) interagency agreement between USAID and PC managed by USAID/Washington. PCVs can access small grants via their country's PC Post. The budget for PMI-supported malaria-specific projects funded by SPA grants typically range from less than $100 to $500, but individual grants may go above this and all grants follow Peace Corps' Small Grants policies and procedures. Funded activities should align the national malaria strategy and may include community dialogues about malaria prevention and control activities, community mobilization activities to increase participation malaria prevention and control activities, health center chats to increase involvement in malaria prevention and control activities, or school health clubs to increase student awareness of and participation in malaria prevention and control activities.PMI teams are encouraged to participate in the application review and award process to ensure that proposed projects align with PMI and NMP priorities; they should make this request to the PC Post. This will also enable the PMI team to follow the implementation of the projects and the use of these funds.

   In some cases, it may be to PMI's advantage to provide support for PCV malaria projects through a PMI implementing partner rather than through the USAID Small Project Assistance (SPA) interagency agreement between USAID and PC. 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.

3. **Funding malaria training events for PCVs and PCV counterparts:** Additionally, PMI can support malaria training events for PCVs and PCV counterparts, however, PMI may not support malaria training events for only PCVs (i.e. without their counterparts). PCV counterparts involved in PMI-supported malaria training events must be directly involved in implementation of malaria prevention or malaria service delivery activities (e.g.. nurse at a clinic, community health worker, district health worker, school teacher involved in school-based prevention activity, etc.). PMI-supported malaria training events for PCVs and PCV counterparts must be coordinated with and endorsed by the NMP. The mechanism to support PCV-facilitated community-level malaria projects and PMI-supported malaria training events for PCVs and PCV counterparts is the USAID Small Project Assistance (SPA) interagency agreement between USAID and PC managed by USAID/Washington. **PMI-supported malaria training events for PCVs and PCV counterparts training events should also be budgeted at maximum $10,000 per year** through the SPA Program.

Training/country orientation

PC historically funded and conducted a comprehensive ten-day Malaria "Boot Camp" training in Senegal that that provided PC MVs – those supported by PMI and those supported by PC directly - with a basic understanding of malaria, key program interventions, and how PC MVs/PCVs can support national strategies at a grassroots level. PMI did not provide funding for this training. As of January 2018, Peace Corps transitioned to a new model, which prioritizes in-country training as well as a virtualtraining. This country-focused model will facilitate capacity strengthening of PCVs together with PCV counterparts, while also allowing for more participation by in-country malaria experts. The PMI team is encouraged to collaborate with the NMP and partners to coordinate and participate in these country-specific trainings for new PC MVs and PCV counterparts, as well as to assist with more in-depth orientation of PC MVs (i.e., sharing the NMP Strategy, current status of malaria control nationally and sub-nationally, key country challenges, and priority activities).In addition to working with the PC MVs, the PMI often participates in PC country-based pre-service, in-service, and even close-of-service training (to provide career guidance).

Supervision, communication, and assessment

PC MVs work under the administrative supervision of the PC country office. PMI in-country staff, designated NMP staff, and implementing partner staff should work together to identify the PC MV's day-to-day supervisor/mentor. If an implementing partner will be supervising a PC MV, then this responsibility should be indicated in the implementing partner's work plan. The PC 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 PC MVs and other PCVs involved with malaria activities to provide opportunity for support, guidance, and mentorship. PMI staff and PC 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 PC MVs have the support and guidance they need.

For additional information on the collaboration between PC and PMI, please contact Andy Tompsett and Irene Cavros.

Field Epidemiology Training Program (FETP)

PMI supports efforts to initiate and strengthen local epidemiologic information and laboratory data collection, management, surveillance, 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 future public health professionals through the CDC FETP national level training efforts. Though the program is implemented with support from CDC, FETP is a country-led program. In 2016, theFETP program was reconfigured 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 Interagency Agreement (IAA) for the advanced program, which consists of a two-year, full-time training program that helps MOHs build sustainable capacity for surveillance system support, data use and analysis, and 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 contribute positive impacts on malaria program efforts following completion of training. FETP residents can serve as resources within the health system to help inform PMI efforts and support malaria surveillance and data activities in addition to providing mentorship opportunities for PMI in-country staff.

In addition to advanced 2-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 twelve total days of didactic training spread over three workshops, interspersed with on-the-job opportunities to apply the training. Frontline FETPs are currently operational in the following PMI focus countries: Angola, Burkina Faso, Cambodia, Cameroon, Côte D'Ivoire, DRC, Ethiopia, Ghana, Guinea, Kenya, Liberia, Madagascar,Malawi, Mali, Niger, Nigeria, Senegal, Sierra Leone, Tanzania, Uganda, and Zambia

Intermediate FETPs are mid-level training programs, targeting either regional level or national program staff. The training duration is typically 9 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, Ghana, Guinea, Kenya, Liberia, Mali, Rwanda, Senegal, Sierra Leone, Tanzania and Thailand. Before writing Frontline or Intermediate support into the MOP, the PMI team should consult with the FETP RA 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, didactic and inductive teaching which includes courses in epidemiology, communications, economics, and management. Trainees also learn quantitative and behavioral-based strategies for mitigating public health problems. The trainees provide epidemiologic services to the Ministry of Health at the national or subnational 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 twelve countries: Cameroon, DRC, Ethiopia, Ghana, Kenya, Mali, Mozambique, Nigeria, Rwanda, Tanzania, Uganda, and Zambia as well as the intermediate FETP in Burkina Faso and Frontline trainees in a handful of countries

Field Epidemiology Training Program residents/participants may be drawn from NMP staff or from other applicants nominated by the Ministry of Health who have a medical or public health background. FETP residents/participants receive financial support from a variety of funding sources with new funding now provided through the Global Health Security Agenda. PMI country MOP funding can be 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 further below). In addition, PMI country teams must coordinate closely with FETP leaders to ensure support for PMI malaria-specific activities and training for FETP participants. For example, the PMI RAs may provide malaria focused lectures and trainings to FETP participants, and mentorship on malaria-related projects. They also help to coordinate and promote the placement of FETP residents within the NMP for training and field work

and should take the lead in facilitating FETP resident collaboration with implementing partners on PMI-funded activities.

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

Although levels of financial support for malaria-focused FETP residents and the costs of training will vary by country, PMI has established budget guidance parameters for PMI support for FETP. PMI support for FETP trainees is external to the salary provided by the Ministry of Health. PMI support contributes to the CDC program that includes two years of training per trainee and includes tuition towards a certificate or degree (if applicable), a modest training stipend, field site supplies, as well as travel expenses for didactic courses, field investigations, supervision, and scientific conferences. PMI funding for FETP cannot be used to support salaries of FETP RAs or salaries of any FETP residents or any other staff associated with the FETP program. PMI country teams proposing support for FETP trainees should budget between $80,000 to a maximum of $150,000 per trainee per two-year assignment ($40,000 to $75,000 per resident annually) 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 strengthening 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 AFENET, but through a PMI implementing partner. The majority of PMI implementing partners work at subnational levels and would be able to provide the necessary support needed for a successful partnership with the FETP Frontline programs.

PMI country teams should ensure appropriate indicators are in place to document the impact of PMI support for the FETP. PMI's decision to support FETP in the early days of PMI was taken with the expectation that graduates employment following graduation would be tracked in order for PMI to

evaluate the extent to which FETP is building cadres of staff that remain within the MOH, to document how PMI investments in this program 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 (including where applicable advance, intermediate and frontline)
- Total number of FETP trainees graduated
- Total number (percentage) of FETP trainees who are employed by the NMP or MoH 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 (especially if a malaria outbreak investigation or malaria elimination activity)
- 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 and number of FETP residents trained in malaria/data/surveillance systems

Success stories

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, NMPs, 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.

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 information and communications technology (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 if consultation would be helpful and/or to understand if there are learnings or similar activities from other countries. Communication should be directed to Nathaniel Moller.**

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 *S&I* chapter for details on routine health information systems.
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 included 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 health care 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% between 2010 and 2013 and absenteeism linked to malaria fell from 24.24% in 2011 to 17.53% in 2014. The company has raised a total of 165 million CFA from partners and employees for the intervention and would benefit from TA and better collaboration with the NMP.

Example of #4 - Innovative/Blended Finance for Malaria Funding

PMI, with support from USAID's Center for Innovation & Impact (CII), partnered with the Development Finance Corporation (DFC) and the Health Finance Coalition (HFC) to mobilize a ~$20 million loan guarantee to unlock up to $35.5 million from the Medical Credit Fund (MCF) in working capital loans for small and medium-sized healthcare providers in Ghana, Kenya, Nigeria, Tanzania, and Uganda. This financing will enable healthcare providers to stabilize operations, procure PPE or other equipment, and continue providing essential health services – including malaria diagnosis & treatment. These loans will be paired with digital training resources from SafeCare on COVID-19 and malaria.[272]

Example of #7 - Extend reach of national messaging campaigns

[272] PMI Announces Emergency Loan Guarantee Facility to Shore Up Private Sector Health Care for Malaria During COVID-19

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 2-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 PSE Toolkit

PMI has invested in the development of a PSE toolkit to help enable NMPs, 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, and supply chain strengthening. The volunteer(s) can be mutually selected by PMI, the NMP 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 NMP priorities and capacity strengthening. Introductory information about this partnership opportunity can be found here. If interested, please reach out to Nathaniel Moller and Hailey Kieltyka.

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) recently launched the Healthcare Electrification and Telecommunication Alliance (HETA). The Global Development Alliance (GDA) is a

five year program with the goal of providing electricity to 10,000 healthcare facilities in sub-Saharan Africa.

PMI country teams who are interested in HETA 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.
- Clarify the Partners, 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 which private sector partners under the GDA are interested in specific geographies, the leverage from those partners, and the number of facilities that can be electrified during initial discussions as an input into the decision to use PMI funds for HFE.

For more information or if there is interest, please reach out to Power Africa's points of contact, Gina Cady and Julius Svoboda, or PMI's points of contact for the partnership, Nathaniel Moller and Jordan Burns.

Rotary

PMI has an opportunity to engage with local private sector business leaders through a partnership with Malaria Partners International (MPI), a not-for-profit organization run by Rotarians. Rotary is a nonpolitical, 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 Community Health Workers. 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 Hailey Kieltyka and Gabriel Ponce-de-Leon 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. It's 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 Standardized Program Structure and Definitions (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 and/or to share possible ideas and opportunities for PSE.

Localization

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 Ministries of Health 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 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, government-to-government (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 does not have 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.

Prioritizing localization requires 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 also means PMI's assessment tools, programming models, award types, funding arrangements, staffing patterns, performance incentives, budget allocations, and

the way that PMI defines results will have to continue to evolve 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.

Background

On November 4, 2021 Administrator Power outlined her priorities for USAID. She committed USAID to achieving specific targets including 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 is supporting the Agency in reaching these targets.

USAID's new Local Capacity Strengthening Policy (2022) establishes a common set of principles to guide USAID's approach to strengthening local capacity and reinforces USAID's commitments to diversity, equity, and inclusion. The Global Health Bureau's Local Capacity Strengthening Implementation Guide (internal to USAID) helps to translate this policy into action by supporting USAID Mission and Washington health teams to consider local capacity strengthening throughout program design and implementation.

Over the past 17 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 Malaria Operational Plan (MOP) process, as prime and subaward implementing partners (IPs), 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 case management, 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 operational research 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 social behavior change 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 2021-2026 strategy and the re-ignited focus within USAID on localization, PMI has an opportunity to expand and improve the way it pursues locally led development in our partner countries. PMI country teams are encouraged to proactively consider increasing the use of local partners during MOP and funding mechanism planning.

PMI's Localization Vision

Achieving PMI's 2021- 2026 strategic goals of preventing malaria cases and reducing malaria deaths requires 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 means an individual, a corporation, a nonprofit organization, or another body of persons that— (1) is legally organized under the laws of; (2) has as its principal place of business or operations in; (3) is majority owned by individuals who are citizens or lawful permanent residents of; and (4) managed by a governing body the majority of who are citizens or lawful permanent residents of a country receiving assistance from funds appropriated under title III of*

this Act." ("Act" refers to Section 7077 of Public Law 112-74, the Consolidated Appropriations Act, 2012 (P.L. 112-74), as amended by Section 7028 of the Consolidated Appropriations Act, 2014 (P.L. 113-76))

Partner government ministries (e.g., Ministry of Health), subunits of government ministries, and parastatal organizations are considered local partners as part of the definition above. A parastatal organization may be a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations.

USAID and PMI consider national and local governments to be critical local partners; nevertheless, government is not counted as part of USAID's target for 25% of funding to go directly to local organizations. Instead, USAID's goal to increase funding to governments is captured in USAID's 50% target around local leadership. Government-to-government funding is also being tracked separately since USAID wants to see funding through government-to-government assistance increase as part of its localization agenda.

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 prioritize 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 agency-level Localization Working Group. These definitions may be refined as the USAID releases additional guidance around localization.

Community Based Organization (CBO)– not for profit organization 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 (CLOs)– 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– 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– 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 (including local partners) 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 community-led organizations, 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 experiences working with local partners as well as learning from other PMI countries' experiences. 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 are involved in the process of 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 completed through an existing partner.
- Increase community participation in PMI's decision-making process, such as by actively inviting feedback from community led organizations 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 may require additional staff expertise and time. PMI countries may want to consider strengthening 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 existing and new 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.

- Government-to-government (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 Rima Shretta, PMI's representative on the Global Health Bureau's G2G working group, with any specific questions.
- The Global Health Bureau's Locally Capacity Strengthening Implementation Guide includes 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; and
    - 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 malaria case management, 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 and universities to lead the design, development, and execution of operational research studies. This draws 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 routine health information systems 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 (G2G)

Direct government-to-government (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. USAID sees government-to-government assistance as an integral part of its localization agenda. 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 NMPs 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 Ministry of Health, 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 community health worker payments and strengthening supply chain systems. Technical assistance and support to the Ministry of Health, NMPs, 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, Madagascar, Mozambique, and Senegal with initiatives that range from technical support to operational research.

Reach out to Rima Shretta as 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

Table 2 of the MOP includes a column 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 to track its investments in local partners in order to help PMI meet its strategic objectives.

Important Resources:

- Administrator Power on a **New Vision for Global Development**
- USAID's new public **Localization webpage**, including vision and approach
- USAID **Locally Led Development Toolkit** (internal), offers resources for working with local partners and catalyzing local leadership
- USAID's **Local Capacity Strengthening Policy**, lays out key aspects and principles of the Agency's localization approach
- **Global Health Local Capacity Strengthening Implementation Guide** (internal)
- **PMI Strategy 2021-2026: End Malaria Faster**
- **PMI Guide to Partnering with Community Led Organizations**, 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
- **Trainings** on How to Work with USAID for USAID staff and local organizations
- **Workwithusaid.org**, is the USAID's resource hub for new, current, and future partners
- USAID **Risk Appetite Statement**
- **Locally Led Development Washington Mechanisms List** (internal)
- **Stakeholder Mapping Overview Guidance** and **Field Guide** (internal)
- PMI **toolkit** to support country teams with engaging local Rotary clubs

Questions?

PMI HQ staff (Stefanie Evans) is 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

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 NMPs 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 governments, the 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 in country staff, 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.