

# U.S. President's Malaria Initiative FY 2020 Guidance



*August 2019*



# PMI MOP GUIDANCE FOR FY 2020

Contains operational guidance for PMI teams as they embark on MOP visits and prepare to review MOPs.

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## Acronyms and Abbreviations

ACT	artemisinin-based combination therapies
aMOP	abbreviated malaria operational plan
CDC	Centers for Disease Control and Prevention
CRR	country results review
DHS	Demographic and Health Survey
FETP	Field Epidemiology Training Program
FY	fiscal year
GFF	Global Financing Facility
GHSA	Global Health Security Agenda
HQ	headquarters
HSS	health systems strengthening
IAA	inter-agency agreement
IAG	Interagency Advisory Group
IRS	indoor residual spraying
ITN	insecticide-treated mosquito net
IPTp	intermittent preventive treatment for pregnant women
MIP	malaria in pregnancy
MIS	Malaria Indicator Survey
MOH	Ministry of Health
MOP	malaria operational plan
NMCP	National Malaria Control Program
OR	operational research
PC	Peace Corps
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
QA	quality assurance
RA	Resident Advisor
RDT	rapid diagnostic test
SBC	social and behavior change
SMC	seasonal malaria chemoprevention
SM&E	surveillance, monitoring, and evaluation
TA	technical assistance
TWG	technical working group
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

## Scope of Work for Malaria Operational Plan Development

### *Purpose*

The primary objective of the planning visit is to draft a Malaria Operational Plan (MOP) for each country following consultative discussions with the National Malaria Control Program (NMCP) and other key stakeholders. For each year of funding under the U.S. President's Malaria Initiative (PMI), a MOP will be prepared for each country for review by the PMI Interagency Technical Working Group (TWG), the PMI Interagency Advisory Group (IAG), and ultimately for approval by the U.S. Global Malaria Coordinator.

PMI is committed to scaling-up a comprehensive set of interventions for the prevention and case management of malaria that are recommended by the World Health Organization (WHO) for malaria control. Planning teams should ensure that each MOP takes full advantage of all key interventions, including: prevention through indoor residual spraying (IRS) and the use of insecticide-treated mosquito nets (ITNs); prompt diagnosis and effective treatment with artemisinin-based combination therapies; preventive use of drugs including prevention of malaria in pregnancy, and, where appropriate, seasonal malaria chemoprevention (SMC) and proactive use of treatment to promote elimination. The balance of support for these interventions will largely be determined by the local epidemiology of malaria, national strategy, and funding gaps. PMI support should be prioritized to fill gaps in commodities as appropriate, to provide technical assistance across the priority interventions, and to strengthen the data and supply chain systems. Planning teams should also ensure that support is provided for priority activities in key cross-cutting areas: surveillance, monitoring, and evaluation (SM&E); critical program evaluation or operations research; social and behavior change (SBC); and other health systems strengthening.

Prior to the MOP planning visit, the US-based team will have regular communication (usually through periodic team conference calls) with the in-country PMI team which includes USAID Mission health team members. Before the external team members arrive in-country, a decision will have been made about the country's PMI budget allotment for the coming fiscal year so that planning can be done around that figure.

### *MOP document structure*

The U.S. Global Malaria Coordinator has requested that all countries follow a standardized format for their MOPs (both the narrative and tables). The FY 2020 MOP template was revised significantly to emphasize key questions related to programmatic decision making as well as align funding categories between PMI and the Global Fund. All PMI country teams **must** utilize the FY 2020 MOP narrative templates and the FY 2020 MOP table templates when writing their MOPs.

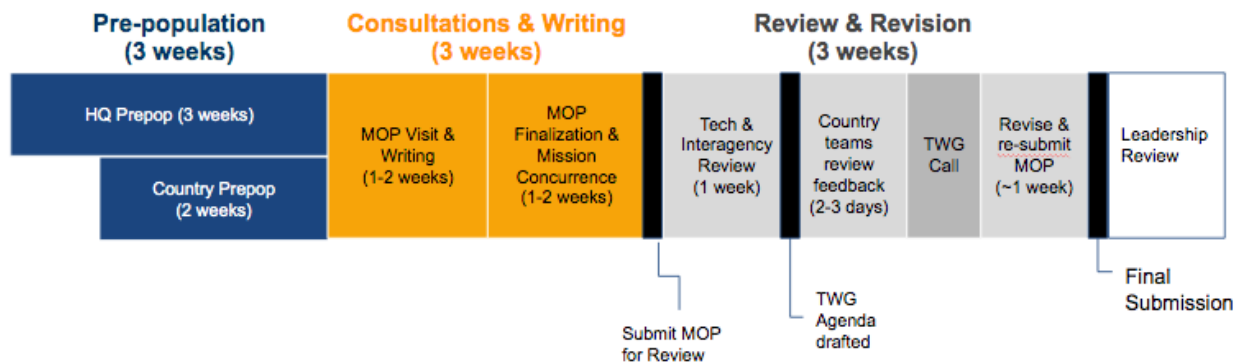
There are a number of new sections starting in FY 2020, including but not limited to:

- **COUNTRY PROGRAM INVENTORY** - This section outlines a high-level program inventory along key intervention areas, and is intended to structure discussions around the relative strengths and challenges facing a program, as well as prioritization and opportunities to drive catalytic impact with specific investments. This section is not meant to be a detailed scorecard or “getting the score right” - and to that end, will be redacted before publication at the request of the NMCP.
- **PARTNER FUNDING LANDSCAPE** - PMI emphasizes the importance of partner alignment on malaria control. In 2018, PMI, GFATM, and BMGF set out to harmonize financial, supply chain, and programmatic data. A harmonized financial taxonomy has been developed for PMI and GFATM (i.e. mapping categories across organizations). The tables in the MOP template summarize contributions by external partners and host country government in calendar year 2018-20, with the goal of highlighting total country investments within the harmonized taxonomy.
- **ANNEX A** - This section seeks to answer key programmatic questions and should be used as a reference when determining and justifying programmatic investments. A majority of the data in this section should be populated during the pre-population process outlined in the *Pre-population section* below.

Templates will be disseminated via email and loaded to [Google Drive](#) no later than 3 weeks prior to the country’s MOP date. If you have questions on how to use the template, please contact Caitlin Christman ([cchristman@usaid.gov](mailto:cchristman@usaid.gov)).

### *MOP Process*

The MOP process is split into three, three-week long sprints: 1) pre-population 2) MOP visit and writing 3) MOP review and revisions. The total timeframe for each MOP, from pre-population through approval should take no longer than 10 weeks.



## Pre-population

New in FY 2020, HQ and country teams are expected to pre-populate MOP data elements in advance of MOP visits to ensure all team members are equipped with the most recent information as well as allow for more time to focus on consultative meetings and financial allocations.

**IMPORTANT:** During the pre-population period the document must stay in the Google environment to allow for simultaneous editing by HQ staff and country teams.

### *Roles & Responsibilities*

Pre-population will be the responsibility of both technical teams based at headquarters and in-country staff. The following is a breakdown of the data types to be entered and by whom:

HQ (SME & Tech Teams) pre-populates:	<b>HH survey information, historical financial info, centrally-managed project information</b> that appears in the following sections: I. Introduction II. Malaria Situation And Malaria Control Progress In Country X III. Overview Of PMI's Support Of Country X Malaria Control Strategy V. Partner Funding Landscape (PMI, GF) Annex: Intervention-Specific Data
Country pre-populated:	<b>HMIS information, non-centrally managed project info, country context, gap analysis tables</b> that appear in the following sections: I. Introduction II. Malaria Situation And Malaria Control Progress In X III. Overview Of PMI's Support Of X Malaria Control Strategy V. Partner Funding Landscape (Gov, other donors) Annex A: Intervention-specific Data (except conclusions)
Not pre-populated	IV. Program Inventory VI. Activities To Be Supported with 2020 Funding (AKA "Table 2") Annex A: Intervention-specific Data (conclusions) Annex B. Summary Of Reprogrammed Activities

### *Timing*

Staff will have access to MOP template via Google Docs no later than 3 weeks in advance of the MOP visit date. If country teams notice discrepancies in data pre-populated by HQ, please reach out to the following team members who will coordinate with tech team POC:

- **Household Survey Data (any section):** Anne Linn [alinn@usaid.gov](mailto:alinn@usaid.gov) & Lia Florey [lflorey@usaid.gov](mailto:lflorey@usaid.gov)
- **Vector Control:** Misun Choi [mchoi@usaid.gov](mailto:mchoi@usaid.gov) & John Painter [bzp3@cdc.gov](mailto:bzp3@cdc.gov)



- **Case Management & Drug-based Prevention:** Lia Florey [lflorey@usaid.gov](mailto:lflorey@usaid.gov), Erin Eckert [eeckert@usaid.gov](mailto:eeckert@usaid.gov) & Lauren Lewis [lwb6@cdc.gov](mailto:lwb6@cdc.gov) & Michael Humes [mhumes@usaid.gov](mailto:mhumes@usaid.gov)
- **SME:** Misun Choi [mchoi@usaid.gov](mailto:mchoi@usaid.gov) and Anne Linn [alinn@usaid.gov](mailto:alinn@usaid.gov)
- **Supply Chain:** Christie Hershey [chershey@usaid.gov](mailto:chershey@usaid.gov) & Lia Florey [florey@usaid.gov](mailto:florey@usaid.gov)
- **SBC:** Anna Bowen [aqb0@cdc.gov](mailto:aqb0@cdc.gov)

## Annex A

A majority of the pre-population will occur in Annex A. Detailed below are the roles and responsibilities within this section.

### Section Background (gray) - Country team to pre-populate

#### J. VECTOR CONTROL

<b>NMCP objective</b>
<ul style="list-style-type: none"> <li>● To deploy data-driven vector control at high coverage (100% IRS coverage of eligible structures or ITNs)</li> </ul>
<b>NMCP approach</b>
<ul style="list-style-type: none"> <li>● <i>National Malaria Elimination Strategic Plan (NMESP) 2017–2021</i></li> <li>● <b>High IRS coverage is primary vector control strategy</b>, with target coverage rate of 80% of population, which may include 50% or less of structures within a district based on eligibility factors (burden, population density, accessibility); guidelines provided for periodic evidence-based rotation of insecticides</li> <li>● <b>Differentiated approach to ITNs in control vs. pre-elimination areas.</b> In control areas, ITNs distributed through mass campaigns every 3 years and continuous distribution through ANC and EPI clinics, primary schools, and communities. In pre-elimination areas, ITNs distributed to those living in IRS-ineligible structures in high burden areas through mini mass campaigns and continuous distribution through ANC, EPI, and selected primary schools</li> </ul>
<b>PMI objective, in support of NMCP</b>
<ul style="list-style-type: none"> <li>● PMI supports all activities in the NMESP 2017-2021, with the exception of XX and YY due to ZZ.</li> <li>● PMI supports this work, with knowledge of other donor plans and mechanisms, which are XX, YY, ZZ.</li> <li>● Specifically, PMI supports entomological monitoring to address insecticide resistance, so that support of ITNs and IRS is well-timed and achieves effective coverage.</li> </ul>
<b>PMI-supported recent progress (past –12-18 months)</b>
<ul style="list-style-type: none"> <li>● Entomological support in 14 of 22 sentinel sites <ul style="list-style-type: none"> <li>○ Insecticide resistance monitoring and comprehensive entomological monitoring (vector parity, biting density, species composition) in 14 sites</li> <li>○ Insecticide resistance monitoring only in 2 sites, Entomological monitoring only (without insecticide resistance) in 2 sites</li> </ul> </li> <li>● IRS campaign supported in 36 districts in four focus regions <ul style="list-style-type: none"> <li>○ TA and operational support provided for mass campaign; 2,438 spray personnel trained</li> </ul> </li> <li>● ITNs Procured: 1.2M of the 9M needed (13%) for 2017-2018 mass campaign <ul style="list-style-type: none"> <li>○ Baseline durability monitoring data collected June 2018</li> </ul> </li> </ul>
<b>PMI-supported planned activities (next –12-18 months, supported by currently available funds)</b>
<ul style="list-style-type: none"> <li>● Conduct entomological monitoring in 14 sites</li> <li>● Procure 694,000 ITNs for continuous distribution; provide TA on continuous distribution, durability monitoring</li> </ul>

**Key Goal (static - do not edit) and funding question (blue) - Do not pre-populate, country team to fill out during MOP visit once funding levels have been determined.**

<b>Key Goal</b>
Determine the geographic distribution, bionomics, and insecticide resistance profiles of the main malaria vectors in the country to inform vector control decision-making
<b>Do you propose to increase, decrease, or maintain funding allocation levels for this activity? Why, and what data did you use to arrive at that conclusion?</b>
We are proposing to maintain similar funding levels for XXX, but, given the identified gap as a result of global fund's allocation cycle, we are proposing an increase in resources towards YY. Given that XX data is still showing low levels of ZZZ, we recognize the need to provide additional funding for QQQ.

**Key Questions (orange) - Supporting data are to be pre-populated by designee in purple highlight. Conclusions are to be drawn by the country team during pre-population or MOP visit.**

<b>Key Question 1</b>	<b>What is the status of care-seeking? [HQ (DHS/MIS); Country (other sources)]</b>																					
<b>Supporting Data</b>																						
<i>Instructions: Insert graph showing care-seeking behavior, from DHS/MIS and/or other sources.</i>																						
<p style="text-align: center;"><b>Trends in Care Seeking for Fever</b></p> <p style="text-align: center;">Among children under 5 with fever in the 2 weeks before the survey for whom:</p> <p style="text-align: center;">■ Care or treatment was sought ■ Care or treatment was sought the same or next day</p> <table border="1"> <thead> <tr> <th>Survey Period</th> <th>Care or treatment was sought</th> <th>Care or treatment was sought the same or next day</th> </tr> </thead> <tbody> <tr> <td>2007 DHS</td> <td>70</td> <td>30</td> </tr> <tr> <td>2008 MIS</td> <td>64</td> <td>64</td> </tr> <tr> <td>2010 MIS</td> <td>31</td> <td>31</td> </tr> <tr> <td>2013-14 DHS</td> <td>75</td> <td>37</td> </tr> <tr> <td>2015 MIS</td> <td>32</td> <td>32</td> </tr> <tr> <td>2018 MIS</td> <td>61</td> <td>20</td> </tr> </tbody> </table> <p style="text-align: center;">*Excludes treatment or advice from a traditional practitioner</p>		Survey Period	Care or treatment was sought	Care or treatment was sought the same or next day	2007 DHS	70	30	2008 MIS	64	64	2010 MIS	31	31	2013-14 DHS	75	37	2015 MIS	32	32	2018 MIS	61	20
Survey Period	Care or treatment was sought	Care or treatment was sought the same or next day																				
2007 DHS	70	30																				
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2010 MIS	31	31																				
2013-14 DHS	75	37																				
2015 MIS	32	32																				
2018 MIS	61	20																				
<b>Conclusion</b>																						
MIS/DHS data suggests that fever is widely recognized as a symptom of malaria and care is routinely sought for children under five with fever. However, care is often not sought in a timely manner.																						

Highlight indicates ownership of pre-populated data

Pre-populated data

Conclusion drawn by country team

## MOP Planning Visit & MOP Writing

Time allocated for MOP visits and MOP writing finalization is three weeks from the day the team begins the MOP visit (in most cases). Though this may seem less than in years past, the pre-population period has shifted some of the content expectations traditionally accounted for in the writing period earlier.

It is expected that the in-country PMI team will play a leading role in writing and editing the MOP, with support from USAID/Washington and CDC/Atlanta. National Malaria Control Programs and other major partners such as UNICEF, WHO, DFID, Global Fund Portfolio Managers and Principal Recipients, and others should be consulted during the preparation of the MOPs, but are not expected to be part of the MOP writing team. Teams are *strongly* encouraged to complete the MOP writing while in country to allow for Mission concurrence to take place the week before MOP due date.

During the planning visit itself, detailed activity plans, timelines, and potential implementing partners will be determined. Each PMI country team should discuss how best to conduct the planning visit. The following is a suggested list of activities for PMI planning visits:

### 1. Reprogramming Requests

As a part of the MOP process, country teams are expected to review prior FY funding and submit relevant reprogramming requests along with that FY MOP document (e.g. when submitting FY 2020 MOP, teams are expected to review FY 2019 and prior allocations). These reprogramming

requests (from any FY) should be added to Annex B and the corresponding Table 2 uploaded to the MOP google drive folder. These requests will be reviewed simultaneously with the MOP document. NOTE: Reprogramming memos may still be submitted at any point in the year as soon as a team has aligned on the requested change(s) and before the change has been implemented at country level. See *Reprogramming Request* section for more information.

## ***2. Meeting(s) with the NMCP/MOH***

Early during the MOP visit, a meeting with the NMCP is recommended to familiarize NMCP staff with the MOP process, elicit feedback on progress on PMI activities and priorities for future support, and engage appropriate members of the NMCP in the planning. It is during this meeting that the Country Program Inventory should be completed in collaboration with the NMCP. Additionally, NMCP staff should be encouraged to participate in field visits and in deliberations over priorities for MOP funding. Once the MOP writing team has reviewed the current status of PMI activity implementation and has a general plan for allocation of PMI funding for the coming year, one or more meetings should be arranged with the NMCP to review the draft plan and get feedback and suggestions. Ideally, the same should be done with other major partners (together with the NMCP) or in separate meetings.

## ***3. Meetings with PMI-funded implementing partners***

The MOP team should meet with the implementing partners to go over progress in the previous year, review challenges, opportunities, and needs in the coming year, and discuss in detail currently funded activities to ensure the program is on track and demonstrating progress on the agreed-upon targets. In many countries, a day-long PMI partner meeting is planned, so that both the MOP team and all USG-funded partners can hear about progress on all aspects of the PMI program, understand where individual implementing partner efforts complement each other, etc. These PMI implementing partner discussions/meetings are separate and distinct from a broader malaria stakeholders' meeting (see #6 below).

## ***4. Internal meetings of the MOP team***

Following these meetings, the MOP team should discuss in detail how PMI will support the identified needs. These discussions involve identifying what mechanisms will be used for programming and how much money should be provided to these mechanisms (to the extent that this can be planned at that stage). These discussions should only include the NMCP (and/or regional/state health authorities), USAID, and CDC. In some cases, it may not be appropriate to have NMCP participation. Some aspects of the plan, such as the budget for staffing and administration and possibly the choice of implementing partners, should not include the NMCP. Missions can provide guidance on this. USAID Health Office Directors/their designee should be included in PMI budget / mechanism discussions. While mechanism discussions often must be internal USG discussions due to procurement sensitivities, decisions on the priority activities and proposed budgets should include our Ministry of Health (MOH)/NMCP counterparts. A good

rule of thumb is to focus on the “what” (what activities at what budget levels are priorities for PMI support) and not the “how” (through what mechanism).

During these meetings, the MOP team also should engage the rest of the USAID Mission health team to determine if there are strategic areas for integration and if there are particular bottlenecks to implementation that would be benefit from systems strengthening efforts.

## ***5. Malaria stakeholders’ meeting***

PMI teams are encouraged to invite all key partners (NMCP, WHO, UNICEF, non-governmental organizations, faith-based organizations, the private sector, implementing partners, multilateral and bilateral donors, etc.) to participate in a stakeholders’ meeting towards the end of the planning visit. The purpose of this meeting is for the NMCP, in collaboration with the MOP team, to present back to partners the major activities that are being considered for implementation support during the coming fiscal year and to get partners’ input and suggestions. A best practice is for the NMCP to lead the stakeholders’ meeting including presenting the planned PMI contributions agreed to during the visit. The forum may also be used to review the progress-to-date of malaria activities in the country and always provides an important opportunity for PMI to demonstrate our transparent, consultative, and inclusive approach to planning. The ultimate product of the stakeholders’ forum is general agreement on the major areas and activities that PMI will consider for support in the next fiscal year. These meetings are best held towards the latter portion of the MOP visit. In rare cases, these consultative stakeholder meetings can occur towards the beginning of the MOP planning visit. However, the downside is that key planning discussions between the PMI team and the NMCP regarding proposed areas of support may not have yet taken place, and thus the initial thinking will not be available to present to stakeholders.

### **Process for decision-making**

To work effectively as an interagency team, the PMI in-country team should communicate jointly with the MOH and NMCP to plan and implement PMI. Any discussions with the MOH/NMCP regarding the planning or implementation of PMI should reflect the collective viewpoints of both USAID and CDC. The in-country PMI Resident Advisors from both agencies should attend any major meetings with the MOH and be equally involved in key decisions. All major decisions including all those that have budget implications must be made with the consent of the USAID/Mission Director or his/her designee.

## **7. Table 2**

Table 2 should be completed while on the MOP visit. Tables have been customized to each country (e.g., countries vs. districts; provinces vs. regions) and will be sent in advance of your FY20 MOP planning efforts. The completed tables should be uploaded to your google folder for submission. NOTE: 1) Due to the excel formulas, the table must stay as an excel file and cannot be opened in google sheets 2) There have been a few new activities added this year having to do with PMI's ongoing financial harmonization efforts. Please see the *Annex: FY 2020 MOP Categories and Corresponding Definitions* for more information.

## **8. PMI MOP debriefing sessions**

Prior to the departure of PMI headquarters MOP team members, the team should summarize key findings and recommendations of the planning visit in debriefing sessions with the MOH/NMCP and USAID/Mission leadership and, when appropriate, the Ambassador. In countries with a CDC office, inviting the CDC Country Director to the USAID/Mission debriefing as a courtesy should be standard. Likewise, in countries with U.S. Peace Corps presence, inviting the Peace Corps Country Director to the USAID/Mission debriefing as a courtesy should also be standard.

## **9. Distribution of draft MOP prior to initiating interagency review**

As part of initial MOP draft finalization, USAID Mission Director concurrence for submission to PMI HQ should be facilitated by the USAID Health Office Director *prior* to MOP submission. The USAID Health Office Director should also share the draft MOP with the Peace Corps Country Director and CDC Country Director as a courtesy for their awareness.

### ***\*Field visits***

MOP planning visits are intense, and based on experience over twelve years with such visits, trying to combine MOP visits with site visits often precludes meaningful discussion of programmatic and technical issues during the site visit(s). Therefore, teams should carefully consider whether a site visit is likely to be a strategic and efficient use of time for the full MOP team. Site visits may be more appropriately grouped with non-MOP related TDYs.

## **MOP Review Process**

### ***Introduction***

PMI/USAID and CDC headquarters staff are called upon to review MOPs in order to (1) ensure technical rigor and adherence to PMI guidance, (2) draw parallels across PMI countries, (3) question assumptions, as appropriate, and (4) ensure that the MOP can be understood by a broad audience. The MOP review process is designed with the goal of supporting country teams to

produce technically rigorous MOPs. The MOP document and collaborative process for developing and reviewing MOPs continue to be cited as major strengths of PMI.

## *Reviewers*

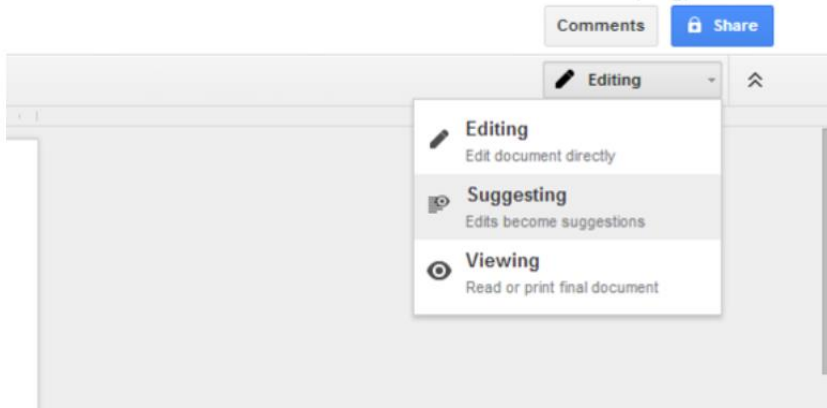
Headquarters staff are trained to review MOPs and are provided norms/expectations for review. In order to maximize reviewers' understanding of the country context and minimize repetitive questions, every effort is made to pair reviewers (both technical and agency reviewers) with countries they have reviewed in the past, and reviewers are asked to read documents from the previous MOP year. In addition, in order to ensure an unbiased, external review, every effort is made not to have members of the headquarters MOP team also be a reviewer for that country (i.e., staff that contribute to the development and writing of a MOP should not be reviewing that MOP)

There are five key individuals/groups of individuals that play a role in the review process:

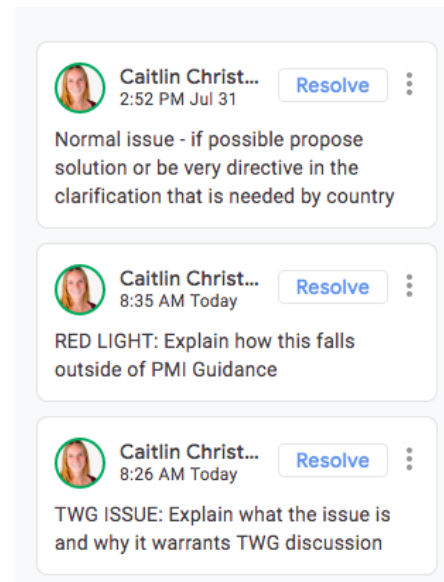
- **MOP Administrator:** A designated administrative support specialist will shepherd the MOP through the review process by providing specific directions, emailing reminders as necessary, and serving as a general resource person for any issues/questions with the MOP portal, deadlines, etc.
- **Technical team reviewers:** Includes a member from each of PMI's interagency working groups as follows:
  - Case Management
  - SBC
  - MIP
  - SMC (where relevant)
  - Elimination (where relevant)
  - Ento/IRS/ITNs
  - SME
  - Supply Chain
  - Operational Research
- **USAID and CDC Agency Leads:** The USAID and CDC Agency Leads review all MOPs and reviewer comments. They also are responsible for chairing the TWG call.
- **Interagency reviewer:** Includes one senior member of the PMI headquarters team. Interagency reviewer (together with Agency Leads) review the entire MOP and are the designated reviewer for the *Other Health Systems Strengthening* sub-section and *Staffing and Administration* section of the MOPs. They also are responsible for developing an agenda for the TWG call, sharing it with the country team and chairing the call.
- **The Global Malaria Coordinator and Deputy Coordinator** approve the MOP as the final step.

## Tracking Issues

The MOP review process will use a Google document platform for submission and review. Reviewers are encouraged to note only substantive technical feedback or questions in the document. Editorial recommended edits should be minimized. All reviewer recommended edits to the MOP should be done in Google doc *Suggesting mode* (see screenshot below).



In order to provide clarity for country teams and to assist the agency reviewers with developing the agenda topics for the TWG, we ask that reviewers denote TWG-Worthy issues by leading with this text “**YELLOW LIGHT**” in the comment that may require additional discussion during the TWG (see screenshot below). If upon reviewing the MOP document there are any activities that fall outside current PMI guidance add a comment leading with “**RED LIGHT**” to explain the issue. Both “Yellow Light” and “Red Light” issues are then to be copied over by the Technical Reviewer into the TWG Issues List.



Country teams will have continuous access to the Google document as reviewer feedback is being added to the document but the document will be locked for edits until the TWG call has been completed. They will also know their reviewers in advance so can reach out with questions during MOP development if they would find this helpful. Country teams will receive a TWG call agenda which lists high-level issues compiled by the Interagency Reviewer. Country teams should come to the TWG call ready to discuss these issues. Call notes will be taken during the TWG. Country MOP Teams will then make edits and finalize the MOP based on these resolutions. There will be not be a Tech Team re-review. Country teams can respond in the Google document with direct changes and comments and are NOT expected to provide a separate set of written responses. All TWG issues should be discussed and resolved within the context of the TWG call.

All comments and suggestions should be addressed by country teams within the context of their MOP resubmission. As a note, we expect for Technical Teams to be in communication with countries throughout the year providing focused technical assistance.

The overall MOP review process is illustrated below:

Tech Review & Interagency Review	Determine issues for TWG discussion, communicate these issues to country and review team	Review Feedback	TWG Call and Resolutions	Revise & Submit MOP	Leadership Approval
1 week	1 day	2-3 days	~2 hours	~1 week	1 week
(Technical reviewers, Interagency reviewers, Agency leads)	(Interagency reviewers)	(Country Team)	(Country Team, Technical reviewers, Interagency reviewers, Agency leads)	(Country Team)	(Global Malaria Coordinator and Deputy Coordinator)

MOP teams should consider the following best practices to reduce the number of issues raised and to ensure adherence to deadlines:

- Adhere to the MOP template
- Seek direct engagement with interagency technical teams to discuss emerging country-specific issues where existing technical guidance is insufficient or unclear
- Designate one or more members of the team to review the MOP in its *entirety* before submission to ensure consistency in language and presentation
- Strictly adhere to all MOP deadlines.



## Writing the MOP: Helpful Hints

The major product of the planning visit is the annual malaria operational plan for each country. It is recommended that the writing of the MOP be completed by the MOP team during their visit and the majority of funding decisions made by the time the team leaves the country. In addition to adhering to the MOP template, please follow the editorial guidelines below:

### *General editorial*

#### Acronyms

- Spell out the acronym the first time it is used, followed by its abbreviation in parenthesis.
  - Ex: The team consulted several times with the National Malaria Control Program (NMCP).
- When spelling out acronyms that are not proper nouns, do not capitalize; e.g. Indoor Residual Spraying (IRS) should be indoor residual spraying (IRS).
- Write “PMI” not “the PMI.” (When not using the acronym, please use “the” e.g. “The U.S. President’s Malaria Initiative started in 2006”)
- If a term is used three times or less in a narrative, do not introduce a new acronym; spell out the term completely.
- In the acronym list, capitalize only the first letter of each term in the list, unless the term is a proper noun, for example U.S. President’s Malaria Initiative.

#### Active vs. passive voice

- Please use the active voice in MOPs and ensure PMI’s contributions are clearly stated. Active voice is preferred because it highlights who is taking the action and is less wordy.
  - Ex.: Passive voice (avoid): A survey of this region was carried out by PMI’s implementing partner in 2006.
  - Ex.: Active voice (use): PMI funded a survey of this region in 2006.
- However, in some cases the passive voice is more appropriate if you want to emphasize the action rather than the actor:
  - Ex.: After much debate, the proposal *was endorsed* by the long-range planning committee.
- Tips for using active voice: If the subject of the sentence is somewhat anonymous, see if you can use a general term, such as “researchers,” or “the study,” or “experts in this field.” Avoid beginning a sentence with *There is* or *There are* because this can easily lead to the construction of a passive sentence.

#### Numbers

- Spell out single digit numbers, one–nine. However:
  - Use numerical form directly before “million” (5 million) or “percent” (2 percent)

- Use numerals when numbers below 10 are grouped for comparison with numbers 10 and above in the same paragraph (e.g., PMI funded 7 surveys in District X and 12 surveys in District Y.)
- Avoid starting a sentence with numerals
- Use only numerals in all tables
- Use “Children under five years of age”, “under-five mortality”

### Writing MOP years

- Use “FY 2020” not “FY20”. However, in tables where space may be an issue, it is acceptable to use “FY20.”
- The MOP describes the activities that will be supported with FY 2020 funding. Please refrain from making statements such as “Activities will be implemented in FY 2020” or “2020 activities in this MOP include X, Y, Z.” Instead, use statements such as: “Activities X,Y,Z will be implemented *with FY 2020 funding*” or “PMI *FY 2020 funding* will support these activities,” or “Planned activities *with FY 2020 funding* include X,Y, Z”.

### Serial commas

- Include serial comma after the next to last item in a list, e.g., “Nigeria, Senegal, and Tanzania.”

### Commonly used words in MOPs

- “stockout” (as a noun) not “stock-out” or “stock out;” however, as a verb, two words: “Stocked out”
- “antimalarials” not “anti-malarials”
- “First-line ACTs”
- “End-use verification survey” (not End use verification survey or End user verification survey)
- “Children under five years of age” not “Children under-five” nor “Under-fives”
- “SBC” not “IEC/BCC” nor “SBCC”

### Other

- Please use Times New Roman, 12 point font, 1.0 (single spacing).
- Avoid redundant writing (e.g., “community-based activity at the community level,” “assessment to assess”).
- Italicize terms that are not in English e.g. *Centrale d’Achats des Médicaments, kebele*, etc.
- When naming a specific geographic unit, capitalize as follows: Kersa District or Oromia Regional State (not Kersa district, Oromia regional state)

# Reprogramming Activities Within PMI Budgets

## *Introduction*

Reprogramming refers to the process by which changes are made to the activities and budget previously approved in MOPs. Since the budgets and mechanisms listed in a MOP are best estimates at the time of development of the MOP and circumstances and needs may evolve and change over time, PMI recognizes the need to reprogram specific activities over the course of the year. Reprogramming memos may be submitted at any point in the year as soon as a team has aligned on the requested change(s) and before the change has been implemented at country level (given Coordinator approval is needed prior to action). Additionally, as a part of the MOP process, country teams are expected to review prior FY funding and submit relevant reprogramming requests along with that FY MOP document (e.g. when submitting FY 2020 MOP, teams are strongly encouraged to review FY 2019 and prior allocations). Country teams will be notified annually of any additional key deadlines to submit reprogramming requests to the U.S. Global Malaria Coordinator, as such deadlines depend on a number of variables and are often linked to timing of annual appropriations bills, availability of fiscal year funding, field support database, internal USAID deadlines, etc.

A reprogramming request must be submitted if:

- A change from one implementing partner to a different implementing partner for the same activity is proposed
- A change in the budget for a given activity is proposed (any financial amount)
- A change to an activity or removal or addition of an activity is proposed
- The implementing partner for an activity, previously listed as “TBD” (to be determined), is determined

There is one exception to the list above. In order to align our IRS categories with the Global Fund, procurement of insecticides for IRS was separated from the category of “IRS Implementation” starting with the FY 2020 MOP. Given insecticide costs for IRS fluctuate based on supply and demand, choice of insecticide, etc., changes between the two categories of “IRS implementation” and “Procure insecticides for IRS” will **not** trigger a reprogramming request.

The reprogramming process described below ensures the accuracy of information and data in the MOPs, including budget, partner(s), activity information and targets, promoting transparency and allowing accurate reporting to Congress. After Coordinator approval, approved revised Table 2 budget plans will be posted on the PMI website. All reprogramming requests should be developed with the involvement of the PMI country team (including at minimum USAID Health Office Director/designee, PMI dedicated country staff, and HQ PMI backstops at both USAID and CDC) and are reviewed through an interagency review process that includes

USAID/Washington and CDC/Atlanta, as well as the Deputy U.S. Global Malaria Coordinator and the U.S. Global Malaria Coordinator.

## *Process*

1. After discussion and agreement is reached within an interagency country team and relevant changes have been communicated to corresponding technical teams (as appropriate), a member of the in-country team (copying the full, interagency country team) should send the reprogramming request to the Reprogramming Request Administrator (Michael Elhardt at [melhardt@usaid.gov](mailto:melhardt@usaid.gov) with a copy to Jonathan Mann at [jomann@usaid.gov](mailto:jomann@usaid.gov)). Once submitted, the request will be electronically routed to each PMI agency lead and their designee(s). Country teams **must** use the reprogramming template provided. A separate reprogramming request is required for each fiscal year's activities.

Corresponding Table 2 must include the following header:

Table 2: Budget Breakdown by Activity  
President's Malaria Initiative - **COUNTRY**  
Planned Malaria Obligations for FY **YEAR (Revised Date)**

2. Each PMI Agency lead has up to five business days to review the request.
  - a. If the agency lead provides clearance, this clearance should be conveyed via email to the Reprogramming Request Administrator.
  - b. If a request does not receive clearance by either agency, the two Agency Leads will discuss, and either come to a resolution and/or request reconsideration and rewriting from the country team. This request will be communicated through the Reprogramming Request Administrator.
  - c. In the event that a resolution cannot be determined through email, the country team is responsible for reaching out to agency lead(s) for further discussion.
3. Once cleared by both USAID and CDC Agency leads, the reprogramming request is forwarded by the Assistant to the U.S. Global Malaria Coordinator to the Deputy U.S. Global Malaria Coordinator for review and clearance and ultimately to the U.S. Global Malaria Coordinator for approval. Once approved and signed, the approved request is returned to the PMI Country team and uploaded to the Reprogramming Request folder on the USAID Shared Drive (P:\PMI\MOPs\Reprogramming requests) along with the revised Table 2. The revised Table 2 is also posted to the PMI website. The total process should be completed within two to three weeks.
4. The PMI Country Team Lead should send both the PDF of the approved request as well as the final Excel Tables 1 and 2 to the in-country PMI team, and help ensure that the Mission program office updates the field support database accordingly.

The advancement of submitted requests can be viewed from any USAID email account on the [Reprogramming Request Tracker](https://goo.gl/Gp2N6v): <https://goo.gl/Gp2N6v>, or PMI staff can ask for clarification

from Michael Elhardt (melhardt@usaid.gov). Experience has shown that a major reason for delays in approval of requests is a lack of sufficient details and rationale about the proposed changes in the original reprogramming request submission. Country teams are encouraged to provide a clear rationale and justification for each requested revision in the reprogramming request. A helpful tip is to assume that the reviewers are not acutely familiar with your country program and thus spell out bilateral project names, provide necessary background, etc.

All reprogramming requests **MUST** be signed by the U.S. Global Malaria Coordinator to be considered approved.

### *When preparing PMI reprogramming requests:*

1. Reprogramming requests must follow the template provided below and should be written in a way that will be understood by a reader who does not have detailed knowledge of the country situation or the MOP. Avoid using abbreviations that are familiar only to members of the country team (including mechanism/project names) and include adequate background information to understand the context of the proposed change.
2. The justification section should provide sufficient details so that a reader who is not familiar with the country situation or the MOP can understand the rationale behind each reprogramming request (i.e., why the budget is being increased or decreased and how that will affect the activity; why the scope of the activity is being changed; or why the implementing partner is being changed).
3. The reprogramming request memo package should include:
  - a. Completed reprogramming request template.
  - b. Excel spreadsheet with revised Table 1 and Table 2. Table 1 and Table 2 should be formatted as described in the MOP guidance document. If a Table 1 or Table 2 is submitted in another format, they will be returned for reformatting.
  - c. Corresponding Table 2 must include the following header:

Table 2: Budget Breakdown by Activity  
President's Malaria Initiative - **COUNTRY**  
Planned Malaria Obligations for FY **YEAR** (**Revised Date**)
4. If an additional change in activity, budget, or partner (as defined above) is made after a reprogramming request has been submitted and approved, a second reprogramming request will be needed.

Questions about the reprogramming memo can be directed to Michael Elhardt <[melhardt@usaid.gov](mailto:melhardt@usaid.gov)> and Jonathan Mann <[jomann@usaid.gov](mailto:jomann@usaid.gov)>

## Annex: FY 2020 MOP Categories and Corresponding Definitions

(Highlights indicate change from FY 2019)

MOP CATEGORY		DEFINITION
1	Support Entomological Monitoring	All-inclusive of entomological monitoring (e.g., insecticide resistance testing, species identification, etc.) <b>except for ITN durability monitoring</b> . For example: technical assistance at national, regional, district level to build capacity for entomologic monitoring; evaluation of in-country entomologic capacity; actual entomological data collection and analysis; support for developing insecticide resistance management plans; support for entomologic staff sitting at NMCP or regional office; procurement of entomologic supplies; etc.
2	Support ITN Durability Monitoring	Budget for ITN durability monitoring (e.g., capacity building, actual data collection, etc.).
3	Procure ITNs for Continuous Distribution Channels	Budget for procurement of ITNs for continuous distribution channels (e.g., ANC, community-based, EPI, schools, etc.), <b>inclusive of cost for delivery from factory to port</b> .
4	Procure ITNs for Mass Campaigns	Budget for procurement of ITNs for mass campaigns, <b>inclusive of cost for delivery from factory to port</b> .
5	Distribute ITNs for Continuous Distribution Channels	Budget for <b>within-country</b> distribution related to continuous distribution channels.
6	Distribute ITNs for Mass Campaigns	Budget for <b>within-country</b> distribution related to mass campaigns.

7	Other ITN Implementation	Includes all other budget figures related to ITN implementation, such as technical assistance (including TA for distribution), microplanning/quantification support, policy and/or guideline development for CD and/or mass campaigns, post net campaign surveys; etc., <b>with the exception of SBC</b>
8	IRS Implementation	Includes almost all budget items related to IRS, such as technical assistance, planning support, payment of spray operators; etc., <b>except for procurement of insecticides</b> (which is captured separately)  <b>If SBC for IRS can easily be broken out, then include under “SBC for Vector Control”. Otherwise, include in this line item.</b>
9	Procure Insecticides for IRS	Insecticide costs for IRS  *New Category: Prior to FY20, used to be captured under “IRS Implementation”
10	Support Independent Environmental Monitoring	Budget for <i>independent</i> environmental compliance inspections (e.g., inspections done by entity <b>other</b> than the implementing partner doing IRS).
11	SBC Implementation for Vector Control	SBC for: <ul style="list-style-type: none"> <li>• ITNs</li> <li>• IRS, only if SBC for IRS is not included under “IRS Implementation”</li> </ul> *New split category. Prior to FY20, grouped all SBC together. Now splitting SBC by vector control, drug-based prevention, and case management. SBC for IRS can either go under this category or under “IRS Implementation” (just note this under the activity description)
12	Procure IPTp-Related Commodities	Includes budget for procurement of SP, DOTS supplies (e.g., cups and water). This is <b>inclusive of cost for delivery from factory to port</b> .
13	MIP Implementation	Includes all other budget items related to MIP, such as technical assistance, support for policy development and guidelines revisions, support for national technical working groups, training and supportive supervision; etc., <b>with the exception of SBC</b> . In many cases, many budget items related to MIP will be reflected elsewhere, such as case Management categories.

14	Procure SMC-Related Commodities	Budget for procurement of drugs, supplies (e.g., cups and water), etc., <b>inclusive of cost for delivery from factory to port.</b>
15	SMC Implementation	Includes all other budget items related to SMC implementation, such as technical assistance, training and supervision, planning; etc., <b>with the exception of SBC.</b>
16	SBC Implementation for Drug-Prevention	SBC for drug-based prevention (e.g., MIP and SMC)  *New split category. Prior to FY20, grouped all SBC together. Now splitting SBC by vector control, drug-based prevention, and case management*
17	Procure RDTs	Budget for procurement of RDTs, <b>inclusive of cost for delivery from factory to port.</b>
18	Procure Other Diagnosis-Related Commodities	Budget for procurement of all non-RDT commodities, such as microscopes, reagents, slides, etc., <b>inclusive of cost for delivery from factory to port.</b>
19	Procure ACTs	Budget for procurement of ACTs, <b>inclusive of cost for delivery from factory to port.</b>
20	Procure Drugs for Severe Malaria	Budget for drugs for severe malaria (e.g., injectable, rectal artesunate), <b>inclusive of cost for delivery from factory to port.</b>
21	Procure Other Treatment-Related Commodities	Budget for all non-ACT and non-severe malaria drugs here (e.g., primaquine), <b>inclusive of cost for delivery from factory to port.</b>
22	Support Therapeutic Efficacy Study	Budget for therapeutic efficacy studies.
23	Support Facility-Based Case Management	Includes all budget items related to facility-based case management implementation, such as OTSS, technical assistance, supervision and trainings, etc., <b>except for SBC.</b>  *New split category: Prior to FY20 MOP, this was grouped under “Other Case Management Implementation”*



24	Support Community-Based Case Management	Includes all budget items related to community-based case management implementation (e.g., PECADOM, iCCM, CHWs), such as OTSS, technical assistance, supervision and trainings, etc., <b>except for SBC</b> .  *New category: Prior to FY20 MOP, this was grouped under “Other Case Management Implementation”*
25	Support Private Sector Case Management	Includes all budget items related to private sector case management implementation, such as OTSS, technical assistance, supervision and trainings, etc., <b>except for SBC</b> .  *New category: Prior to FY20 MOP, this was grouped under “Other Case Management Implementation”*
26	National-Level Support for Case Management	Support for policy development/revisions, technical working groups, case management-specific staff seconded to NMCP, etc.  *New category: Prior to FY20 MOP, this was grouped under “Other Case Management Implementation”*
27	Other Case Management Implementation	Includes any activities that do not fit under “Support Facility-Based Case Management”, “Support Community-Based Case Management”, “Support Private Sector Case Management”, and “National-Level Support for Case Management”
28	SBC Implementation for Case Management	SBC for Case Management  *New category. Prior to FY20, grouped all SBC together. Now splitting SBC by vector control, drug-based prevention, and case management*
29	Warehousing and Distribution	Budget for warehousing and <b>within-country</b> distribution, such as payments/fees to central medical stores or their equivalent (e.g., in Rwanda and Malawi), refurbishment of warehouses, distribution costs for commodities, etc.
30	Pharmaceutical Management Systems Strengthening	Includes budget for pharmaceutical management systems strengthening, such as LMIS/eLMIS, de-junking, EUV, policy development, etc., <b>except for those activities which fall under “Ensuring Drug and Other Health Product Quality”</b>

31	Ensuring Drug and Other Health Product Quality	Includes budget for drug quality monitoring or accreditation of laboratories for drug quality monitoring; technical assistance for drug quality advocacy (e.g., enforcement); etc.  *New category: Prior to FY20, used to be captured under “Pharmaceutical Management Systems Strengthening”*
32	Support Surveys	Budget for household surveys (e.g., MICS, MIS, DHS), facility surveys (or health facility assessments), A&P surveys. <b>Excludes EUVs.</b>
33	Support Routine Surveillance	Budget for routine surveillance, such as IDSR, HMIS, DHIS, etc.
34	Other SM&E Implementation	Includes budget for training for NMCP staff in SM&E, mission M&E activities, evaluations (end of project evaluations, impact evaluations); data quality assessments (DQAs), etc.
35	SM&E for Elimination	Budget for outbreak monitoring in pre-elimination settings, surveillance for elimination, etc.
36	OR Implementation	Includes support for OR implementation.
37	Other Health Systems Strengthening Implementation	Includes budget for support for WHO/NPO, health finance, leadership and governance, NMCP attendance at trainings/conferences, strengthening capacity of local NGOs to implement malaria control efforts, support to NMCP to enable program supervision or supportive supervision at the district level (unless that supervision is intervention-specific), etc.
38	Support to Peace Corps	Budget for support for PCVs and SPAs.
39	Support to FETP	Budget for support for FETP.
40	USAID In-Country Staffing and Administration: Staffing	Budget for USAID In-Country Staffing.

41	USAID In-Country Staffing and Administration: Administration	Up to 2% administration maximum (see PMI Policy).
42	CDC In-Country Staffing and Administration	Budget for CDC In-Country Staffing and Admin.
43	Vector Control-Related CDC TDY	Budget for CDC TDY(s) for entomologic monitoring, ITNs, and/or IRS.  *New collapsed category: Prior to FY20, used to be split into Entomologic-Related CDC TDY, ITN-Related CDC TDY, and IRS-Related TDY.
44	MIP-Related CDC TDY	Budget for CDC TDY(s) for MIP.
45	SMC-Related CDC TDY	Budget for CDC TDY(s) for SMC.
46	Case Management-Related CDC TDY	Budget for CDC TDY(s) for Case Management.
47	SBC-Related CDC TDY	Budget for CDC TDY(s) for SBC.
48	SM&E-Related CDC TDY	Budget for CDC TDY(s) for SM&E.
49	OR-Related CDC TDY	Budget for CDC TDY(s) for OR.

*As of 7/16/2019*



# PMI TECHNICAL GUIDANCE FOR FY 2020

Contains technical guidance for PMI teams and is updated annually to reflect the most recent global policies and the state-of-the-art of malaria control.

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

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## Acronyms and Abbreviations

ACCM	all-cause child mortality
ACT	artemisinin-based combination therapies
ANC	antenatal care
AQ	amodiaquine
CDC	Centers for Disease Control and Prevention
CHW	community health worker
CN	concept note
COR	contracting officer's representative
CPIR	commodity procurement information request
DOT	directly observe therapy
DHS	Demographic and Health Survey
DHIS2	District Health Information System 2
DP	dihydroartemisinin-piperaquine
EIR	entomological inoculation rate
EPI	expanded program on immunization
EUV	end-use verification
FANC	focused antenatal care
FETP	Field Epidemiology Training Program
FIND	Foundation for Innovative New Diagnostics
FY	fiscal year
G2G	government-to-government;"
G6PD	glucose-6-phosphate dehydrogenase
GMP	good manufacturing practices
HFS	Health Facility Survey
HLC	human landing catches
HMIS	health management information system
IAA	inter-agency agreement
ICT	information and communications technology
iCCM	integrated community case management
IDSR	integrated disease surveillance and response system
IMCI	integrated management of childhood illness
IPT	intermittent preventive treatment of women
IPTi	intermittent preventive treatment of malaria in infants
IPTp	intermittent preventive treatment of malaria during pregnancy
IRS	indoor residual spraying
ISTp	intermittent screening and treatment during pregnancy
ITN	insecticide-treated mosquito net
IVM	integrated vector management
K13	kelch protein on chromosome 13
KAP	knowledge, attitude, and practices
LLIN	long-lasting insecticide-treated mosquito net
M&E	monitoring and evaluation

MDA	mass drug administration
MERG	Monitoring and Evaluation Reference Group
MICS	Multiple Indicator Cluster Survey
MIS	Malaria Indicator Survey
MFO	mixed function oxidase systems
MIP	malaria in pregnancy
MOH	Ministry of Health
MOP	malaria operational plans
MSAT	mass screen and treat
NDA	new drug application
NgenIRS	next generation IRS
NGO	non-governmental organization
NMCP	National Malaria Control Program
OR	operational research
PARMA	PMI Antimalarial Resistance Monitoring in Africa
PBO	piperonyl butoxide
PC	Peace Corps
PCR	polymerase chain reaction
PCV	Peace Corps Volunteer
PCW	positive control well
PEA	programmatic environmental assessment
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PMS	post-marketing surveillance
POC	point of contact
PPMRm	procurement planning and monitoring report for malaria
PQ	Pre-Qualification Program
ProACT	Proactive community treatment
QA	quality assurance
QC	quality control
RBM	RBM Partnership to End Malaria
RDT	rapid diagnostic test
RHIS	routine health information system
SARA	service availability and readiness assessment
SBC	social and behavior change
SEA	supplemental environment assessment
SM&E	surveillance, monitoring, and evaluation
SMC	seasonal malaria chemoprevention
SMS	short message service
SP	sulfadoxine pyrimethamine
SPA	service provision assessment
SRA	stringent regulatory authority
TA	technical assistance
TES	therapeutic efficacy study
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

US FDA      United States Food and Drug Administration  
USG          United States Government  
WHO         World Health Organization  
WHO PQ     World Health Organization Pre Qualification (previously WHOPES)

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# VECTOR MONITORING AND CONTROL

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

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

PMI supports evidence-based deployment of traditional and new vector control tools (e.g., new insecticides for IRS and new types of ITNs) to ensure effective vector control in areas of resistance.

**New IRS Insecticides:** In addition to Ficam (bendiocarb) and Actellic (pirimiphos-methyl), two new insecticides are available for IRS: SumiShield (clothianidin) and Fludora Fusion (clothianidin + deltamethrin).

**New types of ITNs:** Piperonyl butoxide (PBO) + pyrethroid ITNs are now available for procurement and dual insecticide ITNs, including the Interceptor G2 (chlorfenaypr + alphacypermethrin) and Royal Guard (alphacypermethrin + pyriproxyfen) ITNs are available through the UNITAID New Nets Project.

Guidance on the selection, rotation, and monitoring of vector control tools with new insecticide classes is included in the **Entomological Monitoring, ITN, and IRS** chapters.

Two of PMI's main interventions – insecticide-treated mosquito nets (ITNs) and indoor residual spraying (IRS) – are aimed at controlling mosquito populations. These two interventions rely on a limited number of insecticides, many of which have been compromised by resistance. PMI supports deployment of traditional and new vector control tools (e.g., new insecticides for IRS and new types of ITNs) through integrated vector management (IVM) strategies to provide effective vector control in the face of insecticide resistance. Entomological surveillance, including monitoring of insecticide resistance, vector bionomics, IRS quality, and ITN durability, is critical to the selection, implementation, and assessment of vector control interventions. It is important that National Malaria Control Programs (NMCPs) develop integrated vector management strategies that articulate how and where ITNs and IRS will be strategically deployed and monitored to provide the highest quality and greatest programmatic impact and mitigate the threat of insecticide resistance. In some limited situations, deployment

of additional interventions such as larval source management (LSM) or topical repellents may be indicated.

## New ITN and IRS Products

The WHO Pre-Qualification Team (WHO PQ) now leads evaluation of vector control products.<sup>1</sup> In the past year, two new products with new classes of insecticide have received WHO PQ recommendation: Fludora Fusion for IRS, and the Royal Guard ITN. With the addition of these new products, PMI now supports deployment of three products for IRS - Actellic (organophosphate), SumiShield (neonicotinoid), and Fludora Fusion (neonicotinoid + pyrethroid) - and two new types of ITNs - PBO synergist and dual insecticide (i.e., Interceptor G2 and Royal Guard) ITNs. Please see below and the **IRS** and **ITN** chapters for further guidance on where and how to deploy these tools.

## Entomological Monitoring

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

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

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

## Evidence-Based Selection of Vector Control Interventions

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

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<sup>1</sup> <http://www.who.int/pq-vector-control/en/>

Insecticide resistance poses a major threat to gains made with core vector control interventions. Standard pyrethroid ITNs have been shown to provide protection even in areas with moderate pyrethroid resistance.<sup>2</sup> In the presence of high pyrethroid resistance (as defined by low mortality frequency or strong resistance intensity across multiple sites), ITNs still provide a physical barrier. In the context of intense pyrethroid resistance, PMI-supported countries should consider transitioning to new types of ITNs (e.g., PBO synergist or dual insecticide ITNs) where supported by insecticide resistance monitoring data, or the addition of IRS in these areas. ITN type and insecticides for IRS should be selected according to entomological monitoring data and rotated as outlined in the **ITN** and **IRS** chapters. Co-deployment of IRS with pirimiphos-methyl and PBO synergist ITNs is not currently recommended, as further investigations are needed to determine if there is an antagonistic effect between the two chemicals.<sup>3</sup> There is currently no guidance with regard to co-deployment of IRS and dual insecticide ITNs (e.g., Interceptor G2s).

## Frequently Asked Questions for Vector Monitoring and Control

### Q1. Are there any other vector control-based technologies that PMI funds can support?

A. No. At the present time, there is inadequate evidence base to support malaria vector control other than by ITNs or IRS in most areas of PMI-supported countries. In some limited circumstances LSM or topical repellents may be indicated. However, as new tools become available and receive a WHO policy recommendation for malaria control, PMI will develop policy and technical guidance for use within PMI supported program efforts. An overview of new tools under review by the WHO Vector Control Advisory Group (VCAG) can be found at <https://www.who.int/vector-control/vcag/en/> and those in development through the Innovative Vector Control Consortium can be found here: <http://www.ivcc.com/creating-solutions/our-work/new-vector-control-tools>.

LSM, which involves the destruction of larval habitats via draining or filling or the application of larvicides has been successful historically in Europe, Brazil, Africa, and Southeast Asia. Modern randomized controlled trials are few, but those that exist indicate that LSM as a standalone intervention, unless conducted with a high degree of rigor, is inadequate. LSM is generally thought to be most appropriate where larval habitats are few, fixed, and findable. This has generally translated to urban settings, areas with seasonal transmission, and lower transmission areas where mosquito larval habitats are destroyed or treated.. While PMI does not prioritize PMI resources to support LSM, there may be instances in the context of elimination where PMI would support LSM (see **Elimination** chapter, '*Entomological Monitoring and Vector Control*' section). WHO's interim position statement on larval source management for sub-saharan Africa

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<sup>2</sup> Lindblade et al. 2015. A cohort study of the effectiveness of insecticide-treated bed nets to prevent malaria in an area of moderate pyrethroid resistance, Malawi. <http://www.malariajournal.com/content/14/1/31>

<sup>3</sup> WHO 2017. Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide. <https://www.who.int/malaria/publications/atoz/use-of-pbo-treated-llins/en/>



indicates that larviciding can be considered as an additional tool to supplement IRS or ITNs for malaria control, but only in those areas where breeding sites are “few, fixed, and findable”.<sup>4</sup>

Other technologies under development, but not yet deployed, include treated clothing and shelter materials, attractive targeted sugar baits, eave tubes, housing improvements, as well as topical and spatial repellents. Since topical repellents clearly reduce mosquito biting, their deployment in elimination settings with difficult to reach populations exposed to outdoor biting may be indicated. These potential tools are being developed by a number of commercial groups as well as the U.S. Departments of Agriculture and Defense:

[http://www.ars.usda.gov/research/projects\\_programs.htm?modecode=60-36-05-15](http://www.ars.usda.gov/research/projects_programs.htm?modecode=60-36-05-15).

PMI will initiate an OR study in 2019 to investigate the effectiveness and potential to scale-up housing modifications. The study will be conducted in Uganda and will include an evaluation of eave tubes, eaves ribbons, and house screening in combination with PBO LLINs.

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

**A.** Some mosquito control strategies are not recommended by PMI for programmatic implementation in Africa. These include: (1) environmental manipulation and biocontrol agents (it is the rare context where this can be effectively implemented); (2) attacking the adult stages through aerial or space spraying of insecticides by ultra-low volume or fog applicators (except in the most rare emergency settings, this is never recommended for malaria control); (3) personal protection through topical and spatial repellents and coils, except under limited circumstances in the Mekong and (4) grass cutting (this has been shown to have NO impact on malaria and should not appear in any control strategy).

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

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# ENTOMOLOGICAL MONITORING

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## Introduction

Since 2000, the scale up of interventions for malaria control including vector control and improved case management has led to dramatic reductions in the malaria burden in Africa with prevalence declining by 50% and the incidence of clinical disease by 40%. Much of the decline has been attributed to the scale up of vector control, with insecticide treated nets (ITNs) and indoor residual spraying (IRS) estimated to account for 68% and 10%, respectively, of the cases averted<sup>5</sup>. The contribution of vector control to the reduction in malaria burden is a reflection of both their effectiveness as well as the substantial investment in scaling up ITNs, in particular. Most countries now aim for universal coverage with at least one vector control tool and vector control accounts for a major share of PMI's budget.

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

1. **Insecticide susceptibility testing** of relevant vector mosquito species to guide selection and rotation of insecticides for IRS and/or ITNs.
2. **Vector bionomics monitoring** to inform selection and timing of vector control intervention as well as to evaluate their quality and impact.
3. **Quality and performance assessments of IRS and ITNs** to determine insecticide residual efficacy and ITN durability (see **ITN** chapter for guidance on durability monitoring).

The overall aim of entomological monitoring is to answer specific questions to inform programmatic decision making. This means that entomological monitoring is not a static process, as each year certain questions will be answered, and other questions will arise. While it is expected that resistance monitoring will be conducted every year, the insecticides used will vary depending on the insecticides currently available for vector control. Similarly, it is important to understand the biting times of mosquitoes, but unless specific behaviors (or changes

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<sup>5</sup> [Nature](#). 2015 Oct 8;526(7572):207-211.

in behaviors) are being investigated, it could be a waste of resources to determine that *Anopheles gambiae* s.l. primarily bites during the night. While this example is an oversimplification, the point is that the questions to be answered should be assessed before determining the activities of entomological monitoring.

## **Insecticide Resistance Monitoring**

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

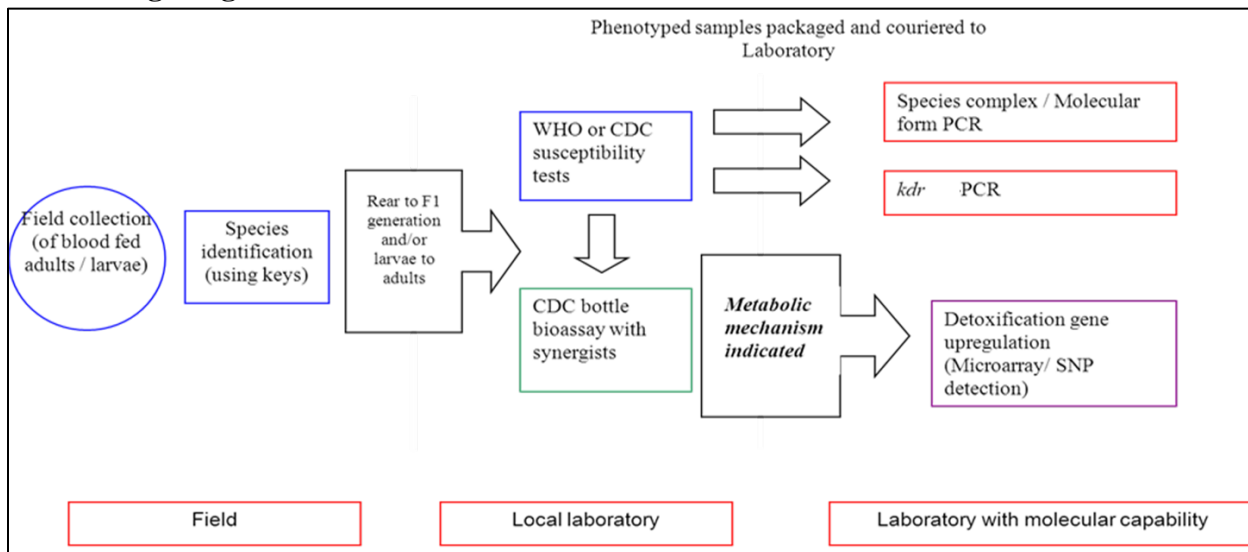
1. Generate data to support the selection of appropriate insecticide for use in ITNs or IRS.
2. Assess the distribution, frequency, and underlying mechanisms, and likely operational impact of any resistance observed.

The concept is simple, though the details can be complex: match insecticides delivered (whether via LLINs or IRS) to measured susceptibility patterns of target mosquito populations. This section provides guidance for monitoring of insecticide resistance in PMI focus countries, including site selection, prioritization of insecticides, testing methods, cut-off criteria and responses, as well as molecular identification of resistance mechanisms. The basic monitoring steps that should be performed are illustrated in **Figure 4** and described below.

### ***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 districts 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 procurement. In countries with large numbers of such sites, regional sampling could be considered. Countries should consult with the Vector Monitoring and Control Team to design a useful and cost-effective sampling scheme. Once monitoring sites are established, baseline insecticide susceptibilities should be determined before interventions are implemented.

**Figure 4. Simplified Diagram of Recommended Steps in an Insecticide Resistance Monitoring Program**



Source: Insecticide Resistance Action Committee, 2011, *Prevention and Management of Insecticide Resistance in Vectors of Public Health Importance*

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

Currently, there are six classes of insecticides recommended for use in adult malaria vector control. Pyrethroids are the most widely used class of insecticides as until 2017, these were the only insecticides recommended for use on ITNs. In 2017, the Interceptor G2 was introduced as a long-lasting insecticidal net (LLIN). This product includes both a pyrethroid (alphacypermethrin) and a pyrrole (chlorfenapyr) insecticide. Several products include a pyrethroid and piperonyl butoxide (PBO), a synergist that may mitigate pyrethroid resistance that is due to increased oxidase activity. A recent study in western Tanzania indicated substantial improvement in effectiveness in context of oxidase based resistance. Further, LLINs incorporating the growth regulator pyriproxyfen showed promise in early studies. The range of insecticides that can be delivered via LLINs is thus expanding.

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

Further background information on insecticides used in vector control for public health, including their safety and efficacy, can be found at the WHO PQ Team website (see <https://www.who.int/pq-vector-control/en/>). An excellent resource for learning more about the modes of action is the Insecticide Resistance Action Committee (<http://www.irc-online.org/>). Ideally, susceptibility testing should be done for the full range of insecticides. In practice, limitations on the numbers of mosquitoes for testing preclude this. Therefore, insecticides for testing should be prioritized based on the vector control intervention(s) being implemented (ITNs, IRS, or both), as this data can provide immediately actionable information, as well as any historical insecticide resistance data. As new insecticides are recommended for IRS or use on LLINs, it is important to include these for baseline testing and to assess whether products with the new insecticides should be considered for procurement.

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

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

Testing for carbamates (bendiocarb) or DDT are only recommended if these insecticides are currently being used. 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. Guidance on how to use these results to inform IRS insecticide procurements and development of rotation strategies is provided in the **IRS** chapter.

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

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

Pyrethroid susceptibility tests and PBO synergist assays should be conducted in parallel where possible to maximize resources. Assays with PBO pre-exposure should be done starting with the lowest insecticide dose as this often restores susceptibility. It should be noted that PMI does not currently procure any alphacypermethrin + PBO synergist nets, so synergist assays performed with permethrin and deltamethrin should be prioritized. 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.

## *Insecticide resistance intensity testing*

While resistance to a single insecticide within a class is often interpreted to indicate resistance to all insecticides within that class, field data from multiple sites indicate variability in the frequency and intensity of resistance among different pyrethroid insecticides. Molecular data also show that mechanisms of resistance may be specific to certain insecticides within the pyrethroid class. Therefore, resistance intensity assays should be conducted for all pyrethroid insecticides used for the treatment of LLINs (permethrin, alphacypermethrin, and deltamethrin), if and when resistance is detected. In areas where PBO LLINs have been distributed, it is recommended to continue pyrethroid resistance intensity testing to monitor the impact of PBO on pyrethroid resistance profiles over time. According to the WHO guidelines<sup>6</sup>, results from insecticide susceptibility tests conducted using the diagnostic dose should be interpreted as follows:

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

For IRS programs, knockdown or mortality <90% at the diagnostic dose (1X concentration) in either the CDC bottle bioassay or the WHO assay indicates the need to switch to a different class of insecticide. For ITNs, the relationship between insecticide resistance and reduced efficacy is less clear. Therefore, additional bioassays at 2X, 5X, and/or 10X should be performed to assess the intensity of resistance. Cone bioassays with different net products may also indicate an optimal product for procurement.

## *Testing methods*

Insecticide susceptibility tests should be conducted with 2 to 5 day old, non-blood fed, female mosquitoes reared from larvae, or on F1 (first) generation mosquitoes raised from the eggs of field-caught females. Larval collections should cover multiple sites, and eggs for an F1 generation should be from a large number of field-caught females to ensure adequate representation of resistance frequencies in the field populations. Sampling mosquitoes along transects may offer an advantage over isolated monitoring sites in order to get a representative sample of mosquitoes for resistance testing. Mosquitoes should be morphologically identified as vectors, to the best of the technician's ability, prior to the resistance assay.

Where F1 mosquitoes cannot be obtained and field-caught females themselves have to be used for testing, it is likely that resistance will be underestimated, as metabolic resistance often

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<sup>6</sup> Test procedures for insecticide resistance monitoring in malaria vector mosquitoes, 2nd ed. Geneva: World Health Organization; 2016

declines dramatically with age of the mosquito.<sup>7</sup> In contrast, if mosquitoes are collected resting indoors on sprayed surfaces, the F1 generation of these mosquitoes may provide an overestimate of the frequency of resistance. If males are tested due to lack of female samples, the data for each sex should be recorded separately since males are likely to show somewhat more susceptibility in bioassays than females. For both larval and adult collections, collection sites should be close together (e.g., within the same village) and georeferenced. The nearest health facility should also be georeferenced to allow linkage of epidemiological data (e.g., DHIS-2 data) trends with resistance monitoring.

Both the WHO tube test and the CDC bottle bioassay can be used for determining the frequency and intensity of insecticide resistance.<sup>8</sup> It is recommended that one (not both) methods be used for any given insecticide. As the bottle bioassay is readily available now, PMI encourages use of this method particularly for resistance intensity and synergist testing. For pyrethroids in particular, resistance intensity should be measured by exposure of mosquitoes to increasingly higher diagnostic concentrations.

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

All mosquitoes used in insecticide susceptibility tests should be sorted by dead or alive following exposure and preserved for subsequent laboratory analyses for confirmation of species identification and detection of molecular markers or resistance.

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

Current molecular markers of insecticide resistance are limited to target site mutations (e.g., *kdr* for pyrethroids or *ace-1* for organophosphates) and a number of genes related to metabolic resistance and cuticular thickening. Metabolic resistance can be detected by using CDC bottle assays with synergists. Piperonyl butoxide will inhibit mixed function oxidases, s,s,s-tributyl, phosphorotrithioate will inhibit non-specific esterases, and ethacrynic acid, diethyl maleate, or chlorfenethol will inhibit glutathione transferase activity. By exposing mosquitoes for one hour in synergist-treated bottles prior to exposure in insecticide-treated bottles, resistant mosquitoes will return to apparent susceptibility if the inhibited enzyme is responsible for resistance. Alternatively, biochemical assays can be carried out to measure enhanced levels of detoxification

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<sup>7</sup> Note, however, that if sufficient specimens are available, determining the susceptibility of wild-caught, adult mosquitoes may provide additional supplementary information

<sup>8</sup> Prior to 2017, only the CDC bottle bioassay could be used for determining the intensity of insecticide resistance. However, WHO now produces papers at 1x, 5x, and 10x.

enzymes responsible for resistance. Target site resistance can be detected by polymerase chain reaction (PCR) for knockdown resistance (*kdr*) and acetylcholinesterase (*ace-1*) resistance genes.

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

Standard operating procedures (SOPs) for all insecticide resistance monitoring methods are available and can be obtained from the **Vector Monitoring and Control Team**.

## 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 intervention and to evaluate their impact. This will be particularly important as new vector control tools (e.g., new types of ITNs) are rolled out.

### *Site selection and sampling frequency*

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



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

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

### *Entomological indicators*

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

- 1. Species composition, abundance, and seasonality.** Vector species composition, abundance, and seasonality should be monitored to determine which mosquito vectors are present in a given area, their abundance, relative proportions, and distributions over time. The same basic mosquito collection techniques are used to calculate abundance, proportions, and seasonality. These include, where appropriate, human landing collections (HLCs), indoor (pyrethrum spray collections, prokopak aspirations) and outdoor resting (pit traps, clay pots) collections, and CDC light traps. Larval collections may also be conducted, particularly in cases where there may be significant outdoor feeding.
- 2. Indoor and outdoor human biting rates.** Indoor and outdoor human biting rates, defined as the number of mosquito bites per person per unit time, should be determined nightly and/or hourly to understand where and when transmission is most likely occurring. Human landing catches are the preferred method, and are typically conducted overnight from 6:00 pm to 6:00 am, but may be extended depending on local vector behavior. If ethical approval cannot be obtained for HLCs, appropriate alternatives should be discussed and identified in consultation with PMI Entomology backstops. CDC light traps hung next to a person sleeping under an ITN may be used to provide some indication of indoor feeding, but not on the time of feeding or 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), (see <http://www.mr4.org/Portals/3/Pdfs/Anopheles/3.3%20Plasmodium%20Sporozoite%20ELISA%20v%201.pdf>), bead assays or polymerase chain reaction (PCR)(although it should be noted that PCR does not distinguish sporozoite-stage parasites from other stages, so care should be taken in bisection of mosquitoes).
5. **Entomological inoculation rate (EIR).** The EIR is a measure of malaria transmission intensity that describes the number of infectious bites an individual is exposed to in a given time period (typically a year or transmission season). EIR estimates may differ widely depending on sampling methods used and the amount of sampling error, which can be great in areas where mosquitoes are rare and/or rarely infected (as in areas with low parasite prevalence and low transmission). Therefore, EIRs should be interpreted with caution.
6. **Human/animal blood indices.** Analysis of mosquito blood meal sources enables one to determine what portion of mosquito blood meals are taken on humans versus animals. Repeated collections after the introduction of a vector control intervention may be used to identify shifts in feeding behavior. Estimates of host feeding rates are strongly affected by host availability and sampling strategy and should therefore be interpreted with caution. Blood-fed mosquitoes can be collected by indoor or outdoor resting collections or CDC light traps. Blood meal sources can be identified using ELISAs or PCRs.
7. **Parity rates.** Parity rates are monitored to determine the age structure of a vector population. This manner of age grading be a useful indicator as older vector populations

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

For additional information on mosquito collection techniques, WHO’s excellent *Manual on Practical Entomology for Malaria Control* is available for reference (see [http://whqlibdoc.who.int/offset/WHO\\_OFFSET\\_13\\_\(part1\).pdf](http://whqlibdoc.who.int/offset/WHO_OFFSET_13_(part1).pdf) and [http://whqlibdoc.who.int/offset/WHO\\_OFFSET\\_13\\_\(part2\).pdf](http://whqlibdoc.who.int/offset/WHO_OFFSET_13_(part2).pdf)). Training videos are also available for a number of mosquito collection methods at <https://vimeo.com/ivmproject>.

Standard operating procedures (SOPs) for all vector bionomics monitoring methods are available and can be obtained from the **Vector Monitoring and Control Team**. Please consult with PMI USAID and CDC Entomology backstops to develop a molecular entomological monitoring plan, determine appropriate sample sizes, to develop a plan for molecular testing, and for suggested reference laboratories to which samples may be sent.

### ***Mosquito identification***

Accurate mosquito identification underpins all entomological indicators for malaria. As the major vectors of malaria in Africa are species complexes, whereby different species are morphologically identical (e.g., *Anopheles gambiae*, *An. arabiensis*, and *An. coluzzii*) but genetically distinct, a subsample of specimens identified to the species complex level should be sent to a laboratory for molecular identification of species by PCR. Special care should be taken as most PCR-based assays only distinguish between members of a complex, and may result in spurious results if mosquitoes from outside the complex are tested. If PCRs routinely fail to amplify DNA, this may be a sign of incorrect initial morphological identification. DNA sequencing of CO1 or ITS2 targets may help resolve the questions surrounding the identity of the species, but it should be noted that there is not yet a complete understanding of how existing

species and DNA sequences correspond. The number of specimens in this subsample will be determined by the relative abundance of the sibling species, the capacity of the reference laboratory, and the purpose of the molecular identification tests. For example, a smaller subset of samples from larval collections for insecticide susceptibility tests may be identified as a spot check on the accuracy of morphological identification whereas a larger proportion of adult mosquitoes found in houses may be assayed to determine vector species distribution. It should be noted that as vector control efforts have progressed, formerly minor vectors of malaria may become predominant. Molecular identification is a useful adjunct to morphological identification and should be carried out on a sample of specimens where changes in species composition have occurred. Similarly to parity dissections, programs should maintain a reference collection of different species of mosquitoes, and those identifying mosquitoes should be tested frequently.

## **Quality Assurance and Residual Efficacy Monitoring of IRS**

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

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

### ***Test methods***

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

To perform cone bioassays, known susceptible laboratory-reared mosquitoes (e.g., *An. gambiae* Kisumu strain) should be used. If these are not available, wild-caught, unfed, female mosquitoes can be used as long as there is no demonstrated resistance in the population. The process for IRS testing is as follows: (1) attach bioassay cones to walls at three different heights (0.5 meter, 1.0 meter and 1.5 meters above the floor) using tape; (2) introduce batches of 10 female mosquitoes into the cones and expose to the wall surface for 30 minutes; and (3) after exposure, transfer the

mosquitoes to paper cups, provide them with a sugar solution, and record mortality 24 hours after exposure for pirimiphos-methyl or every 24 hours for up to seven days for clothianidin. Tests should be conducted in enough houses to be representative of different wall surfaces and different groups of spray operators. Control assays should also be conducted – either select houses of similar construction that have not been sprayed or cover sprayed wall with two layers of paper before attaching the cones. Introduce 10 mosquitoes per cone as above.

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 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) for IRS quality assurance and residual efficacy monitoring methods are available and can be obtained from the **Vector Monitoring and Control Team**.

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

## **Entomological Monitoring in Elimination Settings**

In areas with declining malaria transmission, marked geographic heterogeneity can become more apparent within regions and among villages. Further, vector numbers may decline markedly, making collections more time-consuming and costly. Heterogeneity and sparse vectors present challenges for entomological monitoring, making long-term trends more difficult to discern. Sample sizes needed to assess insecticide susceptibility may be more difficult to attain. To ameliorate these problems, sampling sites for entomological monitoring should focus on areas where transmission is likely to be occurring, as determined by epidemiological data from the routine health management information system (HMIS). In elimination settings, there should be a subset of sites used for longitudinal monitoring of insecticide resistance (e.g., in addition to a subset that can be chosen yearly in response to changing epidemiology). Foci investigations in response to malaria outbreaks and case follow-up are also recommended. These will include rapid surveys of vector control intervention coverage, assessment of vector and human behavior to determine the locus of transmission, and assessment of the vulnerability of vectors to LSM.

## Entomological Monitoring Supplies

Supplies for entomological monitoring are to be procured via the current central mechanism or a bilateral implementing partner. No entomological monitoring supplies should be budgeted for using the CDC mechanism in FY 2020 malaria operational plans (MOPs), though certain supplies may be provided by CDC (via CDC country entomologists and funded through PMI core funds to the CDC Interagency Agreement (IAA)). Such supplies may include insecticides for susceptibility testing or reagents for molecular analyses (e.g., ELISA or PCR).

## Data Collection and Reporting

Periodic reports of findings in a standardized format should be provided to both the NMCP and PMI headquarters (including entomology team members from both agencies supporting PMI) from each monitoring site. The PMI Headquarters Entomology Team will work with implementing partners to develop this standard format and recommend the frequency of the reports, and will publish all final annual entomology reports online for public access. At minimum, the following should be reported: (1) results of IRS residual activity, measured by cone assay with a susceptible mosquito strain, within the first few weeks of spraying for quality assurance purposes (i.e., if issues with quality are identified re-spraying may be needed), and (2) semiannual reports highlighting the seasonal collections to date and results for all basic entomological indicators.

All susceptibility data from whatever source should be promptly shared with the NMCP and with district and regional malaria control staff. **Current susceptibility data should be submitted to PMI at least 6 months prior to the next spray campaign to allow for evaluation and timely insecticide procurement.** Entomological and epidemiological reports (the latter from local health facilities) should be compared and shared by health officials. Some countries have a national Technical Advisory Committee that includes PMI, which can review entomological monitoring data and make recommendations. PMI country teams should ensure that the PMI Headquarters Entomology Team receives all relevant entomological information and are involved with these discussions.

Additionally, all susceptibility data and cone assay results should be submitted to the PMI Headquarters Entomology Team via PMI's database forms (currently being managed by our global IRS implementing partner). Access to this raw data will enable better analysis of insecticide resistance distribution and trends.

### *VectorLink Collect database*

All countries with PMI-supported IRS programs and most countries with PMI-supported entomological monitoring programs will begin using a new centralized database developed on the DHIS-2 platform, known as VectorLink Collect. The DHIS-2 platform allows for enhanced

data visualization and analytic opportunities which were not previously available under the legacy database system. NMCPs and government counterparts will have access to this system, which will be rolled out in all countries utilizing the vector control central mechanism by the end of 2020, to allow for country ownership of vector control data. Currently, the Entomology instance consists of data collection programs focusing on insecticide resistance, insecticide residual life and vector abundance and behavior data. Pre-programmed analytic objects and dashboards will allow for near-real time analysis and reporting to PMI HQ and country governments of key entomological data as it is directly entered into the system.

To complement this new system, the Vector Monitoring and Control Team is planning on comparing several different mobile data collection systems for entomology (e.g., EpiInfo Vector, etc.) in 2020 to determine if there is an optimal compatible system that could directly feed into the database. If countries are planning on using an already existing system, then please consult with PMI USAID and CDC Entomology backstops to ensure that the system can integrate with the database.

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# INSECTICIDE-TREATED NETS

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## \*New/Key Messages\*

**Selection of new types of ITNs:** PMI supports procurement and targeted distribution of PBO synergist and dual insecticide ITNs according to key criteria (see page 37).

**UNITAID New Nets Project (NNP):** Two dual-insecticide ITNs, Interceptor G2 and Royal Guard, have received WHO PQ approval, though neither has received a WHO policy recommendation. PMI along with the Global Fund are guiding the UNITAID New Nets Project (NNP) to obtain the evidence base needed to inform policy recommendations and catalyze scale-up of these two ITNs. The NNP will subsidize procurement of these nets for a randomized control trial in Benin and Tanzania as well as effectiveness/implementation pilots in multiple PMI-supported countries from 2019 - 2022.

**ITN Durability Monitoring:** All PMI-funded durability monitoring activities should adhere to the guidelines and templates here: [www.durabilitymonitoring.org](http://www.durabilitymonitoring.org)). The final reports are publicly available here: [https://www.pmi.gov/how-we-work/technical-areas/insecticide-treated-mosquito-nets-\(itns\)-pmi](https://www.pmi.gov/how-we-work/technical-areas/insecticide-treated-mosquito-nets-(itns)-pmi). For more information, contact the PMI Headquarters Vector Monitoring and Control Technical team.

**Mass Campaign Calendar:** A mass campaign tracker, detailing the dates, locations, and quantities of ITNs to be distributed across countries and donors, is now available here: <https://allianceformalariaprevention.com/about/>.

**ITN Access and Use Report:** PMI funds secondary analysis of DHS and MIS data from all focus countries to calculate the ratio of use to access, to provide insight into how ITN use may be linked to access, or to other behaviors. This report is available at <http://www.vector-works.org/resources/itn-access-and-use/> (the report is updated within 30 days of the release of new DHS/MIS datasets (not just preliminary report) and circulated to PMI field and HQ teams).

## 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. Insecticide-treated nets were shown to reduce child mortality from all causes by 17% compared to children sleeping without a net. Uncomplicated clinical episodes of



malaria were reduced by almost one-half and severe malaria episodes were also reduced by more than 40%. The prevalence of *P. falciparum* was reduced by 17%. Similar results were found when ITNs were compared to untreated nets, with child mortality from all causes reduced by one-third (moderate-certainty evidence). Uncomplicated clinical episodes of *P. falciparum* were reduced by 42%.<sup>9</sup>

Between 2000 and 2015, it is estimated that over 1 billion ITNs were distributed in malaria endemic countries. The estimated percentage of the at-risk population sleeping under an ITN rose from 30% to 53% between 2010 and 2016. During this time, disease incidence and malaria-related deaths have fallen by 21% and 29%, respectively.<sup>10</sup> Additionally, parasite prevalence in endemic sub-Saharan Africa decreased by 50% between 2001 and 2015, with 68% of this decline attributed to the use of ITNs.<sup>11</sup>

PMI's strategic plan calls for 85% coverage of key malaria interventions. In addition to reducing human-vector contact at the individual level (via repellency of insecticide and physical barrier of net), ITNs also kill mosquitoes or, among those surviving immediate death, reduce longevity and prevent transmission. This overall reduction in transmission provides a "community effect" by which even those residents not sleeping under a net have increased protection from malaria infection. The "threshold" coverage whereby ITNs provide a mass, community effect depends on the ecological context. For programmatic reasons, PMI aims for the target of 85%. However, in certain ecological situations (e.g., where vectors prefer to feed on humans indoors, and there are few alternate hosts available), modeling indicates that the "threshold" for the community effect may be as low as 35-65% of nightly ITN use by adults and children in the community.<sup>12</sup>

## WHO-Recommended Long-Lasting ITNs (LLINs)

In its most recent report, April 2019, WHO has provided a list of current prequalified long-lasting ITN products:<sup>13</sup>

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<sup>9</sup> Pryce J, Richardson M, Lengeler C. Insecticide-treated nets for preventing malaria. Cochrane Database of Systematic Reviews 2018, Issue 11.

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000363.pub3/epdf/full>

<sup>10</sup> World Health Organization. Global Technical Strategy for Malaria 2016–2030. Geneva: World Health Organization, 2016.

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

<sup>12</sup> Killeen GF, Smith TA, Ferguson HM, et al. Preventing childhood malaria in Africa by protecting adults from mosquitoes with insecticide-treated net. *PloS Medicine* (2007) accessed at:

<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040229>

<sup>13</sup> WHO Prequalified Products, Vector Control (11 April, 2019). [http://www.who.int/whopes/Long-lasting\\_insecticidal\\_nets\\_April\\_2016.pdf?ua=1](http://www.who.int/whopes/Long-lasting_insecticidal_nets_April_2016.pdf?ua=1)

### **Pyrethroid Only**

- A to Z Textile Mills Limited: Miranet<sup>®</sup>
- BASF SE: Interceptor<sup>®</sup>
- Disease Control Technologies : Royal Sentry<sup>®</sup>, Royal Sentry 2.0<sup>®</sup>
- Fujian Yamei Industry: Yahe<sup>®</sup>
- Life Ideas Textiles: PandaNet 2.0<sup>®</sup>
- \*Mainpol GmbH: SafeNet<sup>®</sup>
- Shobikaa Impex Private Limited: Duranet<sup>®</sup>
- Sumitomo Chemical Co. Ltd.: Olyset<sup>®</sup>
- \*V.K.A Polymers Pvt. Ltd.: MAGNet
- Vestergaard Frandsen S.A.: PermaNet 2.0<sup>®</sup>
- \*Yorkool: Yorkool<sup>®</sup>
- Fujian Yamei Industry & Trade Co., Ltd.: Yahe LN<sup>®</sup>
- \*NRS Moon Netting FZE: Tsara Soft<sup>®</sup>

### **PBO**

- Sumitomo Chemical Co. Ltd.: Olyset Plus<sup>®</sup>
- Vestergaard Frandsen S.A.: PermaNet 3.0<sup>®</sup>
- \*V.K.A Polymers Pvt. Ltd.: Veeralin<sup>®</sup>
- \*NRS Moon Netting FZE: Tsara Boost<sup>®</sup>
- \*NRS Moon Netting FZE: Tsara Plus<sup>®</sup>

### **Dual AI**

- BASF SE: Interceptor G2<sup>®</sup>
- Disease Control Technologies: Royal Guard<sup>®</sup>

*(\*) Denotes an ITN product not procured by PMI*

While these products employ different technical processes for polyester, polyethylene, and polypropylene 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. PMI only supports the purchase of WHO prequalified ITNs. This table lists all ITNs that have PQ approval. However, PMI does not procure comparator products that do not have field data. Furthermore, PMI is procuring long-lasting insecticide-treated hammocks for distribution in the Mekong region to reach and protect migrant mobile populations.

## **PMI Policy on WHO Equivalency Policy**

The WHO follows an equivalency process that allows new long-lasting ITN products to receive WHO recommendation status based on their chemical equivalency to the innovator net product. These “comparator” products are granted WHO interim or full recommendation status based only on results from WHO chemical laboratory testing. In contrast, to achieve interim

recommendation status, an innovator long-lasting ITN must have appropriate lab and field data. After a technical review, PMI has determined that the equivalency status based only on laboratory studies is insufficient to determine eligibility for PMI procurement because these studies do not determine how the long-lasting ITN product functions in the field where other factors come into play, particularly mosquito behavior around nets. **PMI policy does not currently allow for procurement of the comparator nets unless field testing has been completed.** (For a full discussion of the policy please see: [http://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/itn\\_procurement\\_specifications.pdf?sfvrsn=4](http://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/itn_procurement_specifications.pdf?sfvrsn=4).)

## Selection of ITNs in the Context of Pyrethroid Resistance

Emerging insecticide resistance poses a challenge to current malaria vector control methods, as until recently, there were only four classes of insecticide in use for adult malaria vector control (pyrethroids, organochlorines, organophosphates and carbamates), and pyrethroids are the primary insecticides used on ITNs. Resistance to all four classes has been detected in malaria vectors with widespread resistance to pyrethroid insecticides. As of October 2016, resistance had been reported in 71 malaria-endemic countries.<sup>14</sup> If the trend of increasing frequency of resistance continues, it may result in a reduction of the effectiveness of pyrethroid-based interventions.<sup>15</sup>

Despite widespread resistance to pyrethroids, there is limited epidemiological evidence to date that the personal protective effect of long-lasting ITNs has been compromised with several observational studies showing no correlation between insecticide resistance and malaria incidence.<sup>16</sup> However, PMI remains concerned that intensification of pyrethroid resistance could undermine the gains made in reducing the burden of malaria. Because of the threat of expanding and intensifying insecticide resistance, resistance monitoring should be an essential part of every PMI focus country's vector control strategy. This information will be crucial to better targeting and evaluation of these products in the future. PMI is committed to addressing insecticide resistance by rolling out and rotating new types of nets as they become available. Guidance for entomological and insecticide resistance monitoring are detailed in the **Entomological Monitoring** chapter.

In response to increasing pyrethroid resistance, manufacturers have developed new ITNs with additional active ingredients to combat pyrethroid resistance. There are two new types of ITNs

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<sup>14</sup> Coleman M, Hemingway J, Gleave KA, Wiebe A, Gething PW, Moyes CL. Developing global maps of insecticide resistance risk to improve vector control. *Malar J.* 2017;16:86.

<sup>15</sup> Implications of insecticide resistance for malaria vector control with long-lasting insecticidal nets: trends in pyrethroid resistance during a WHO-coordinated multi-country prospective study. *Parasites & Vectors*, 2018. <https://parasitesandvectors.biomedcentral.com/articles/10.1186/s13071-018-3101-4>

<sup>16</sup> Kleinschmidt I et al. Implications of insecticide resistance for malaria vector control with long-lasting insecticidal nets: a WHO-coordinated, prospective, international, observational cohort study. *Lancet.* 2018 Jun;18(6):640-649. <https://www.ncbi.nlm.nih.gov/pubmed/29650424>

that are on the list of WHO Prequalified Vector Control Products: piperonyl butoxide (PBO) synergist nets and dual-insecticide nets. Two trials have demonstrated improved efficacy of dual-active (pyriproxyfen and permethrin)<sup>17</sup> and pyrethroid-PBO<sup>18</sup> treated ITNs. Two dual-insecticide ITNs, the Interceptor G2<sup>19</sup> and Royal Guard<sup>20</sup>, have received WHO PQ approval, though neither has yet received a WHO policy recommendation. Although WHO has issued interim policy guidance for PBO nets, it has not issued guidance on when to deploy dual-insecticide nets, therefore PMI has separate guidance for each (see below). According to the data available, the unit cost of the new type of ITNs is greater than pyrethroid-only ITNs, although these unit costs may decrease in the future with economies of scale and through the efforts of the [New Nets Project](#).

## PBO Synergist ITNs

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

In 2015, the WHO Global Malaria Program convened an Evidence Review Group on PBO ITNs to review data from numerous laboratory studies, nine experimental hut trials, and six village-level trials with entomological endpoints. The studies provided mixed results, and the Evidence Review Group concluded that the limited evidence did not justify a switch to PBO nets, but was sufficient to justify limited, pilot “exploratory” implementation of PBO nets accompanied by robust evaluation of impact with both entomological and epidemiological indicators. This evidence was recently supplemented by a cluster-randomized trial in Tanzania with epidemiological endpoints. Based on the positive results of this trial, in September 2017 (and

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<sup>17</sup> Tiono AB, Ouedraogo A, Ouattara D, Bougouma EC, Coulibaly S, Diarra A, et al. Efficacy of Olyset Duo, a bednet containing pyriproxyfen and permethrin, versus a permethrin-only net against clinical malaria in an area with highly pyrethroid-resistant vectors in rural Burkina Faso: a cluster-randomised controlled trial. *Lancet*. 2018. [https://doi.org/10.1016/S0140-6736\(18\)31711-2](https://doi.org/10.1016/S0140-6736(18)31711-2)

<sup>18</sup> 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.

<sup>19</sup> N’Guessan R, Odjo A, Ngufor C, Malone D, Rowland M. A Chlorfenapyr Mixture Net Interceptor(R) G2 shows high efficacy and wash durability against resistant mosquitoes in West Africa. *PLoS One*. 2016;11:e0165925.

<sup>20</sup> Efficacy of Three Novel Bi-treated Long Lasting Insecticidal Nets. <https://clinicaltrials.gov/ct2/show/NCT03554616>

updated December 2017) WHO/Global Malaria Programme provided PBO ITNs an interim endorsement as a new class of vector control products.<sup>21</sup> Full confirmation of the class will require data from a second epidemiological trial; a cluster-randomized trial is currently underway in Uganda, with preliminary results expected at the end of 2019. Meanwhile, as stated by WHO's policy guidance, "all pyrethroid-PBO nets that have a WHO prequalification listing (Permanet 3.0, Olyset Plus, Dawa 3.0, Dawa 4.0, and Veeralin) will be considered to be at least as effective at preventing malaria infections as pyrethroid-only ITNs, and possibly more effective in areas of low-to-moderate pyrethroid resistance." WHO's policy recommendation does not consider PBO ITNs to be a tool to effectively manage insecticide resistance in malaria vectors.

**Based on December 2017 WHO policy guidance, PMI will procure PBO ITNs on a case-by-case basis, for use on a sub-national scale, following the data and program requirements outlined below.** If NMCPs or country teams are considering procuring PBO ITNs, the country teams should engage with the PMI Vector Monitoring and Control Technical (VMCT) and Supply Chain teams for further guidance. In general, once a country team requests an order, the Supply Chain team will communicate with the VMCT team to gather data needed for entomological justification.

### *Key data needed to justify procuring PBO ITNs*

The following data should be collected at the district or regional level where PBO ITNs are being considered:

- Current insecticide resistance data (collected within the past year) confirming pyrethroid resistance in the main malaria vector(s).
- Evidence that PBO increases pyrethroid susceptibility by at least 10% (in absolute terms). This could be from:
  - Susceptibility assays combining pyrethroid + PBO
  - ITN cone bioassays with standard and PBO ITNs
- Documented moderate to high malaria prevalence (>20%) in children 2 – 10 years old using existing data sources.

### *Requirements for deploying PBO ITNs*

- Ability to collect entomological data and routine health facility data in the geographic areas of deployment.
- PBO ITNs should not be deployed in the same area as IRS, as there is currently no evidence of added benefit of PBO ITNs in addition to IRS.
- As PBO ITNs are currently more expensive than pyrethroid-only ITNs, the benefit of the PBO ITNs must be weighed against a potential loss of overall ITN coverage. The cost of

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<sup>21</sup> Conditions for deployment of mosquito nets treated with a pyrethroid and piperonyl butoxide, September 2017. Geneva: World Health Organization; 2017. <http://apps.who.int/iris/bitstream/10665/258939/1/WHO-HTM-GMP-2017.17-eng.pdf>

procuring PBO ITNs must be weighed against the effect of reduced resources for other malaria program priorities—they will not be procured if there are key malaria commodity gaps (e.g., ACTs, RDTs) or significant malaria control programmatic gaps.

These criteria must be discussed with the PMI VMCT team in conjunction with country stakeholders (i.e., NMCPs, implementing partners, entomology institutions), using the best available technical evidence, and HQ must provide approval for a PMI focus country to procure PBO nets. If NMCPs or malaria partners are procuring PBO nets with non-PMI funding, please contact the PMI VMCT team to identify the appropriate partnership role PMI may play.

## Dual-Insecticide ITNs

Dual-insecticide nets are ITNs that have both a pyrethroid, plus a second insecticide of a different class. Unlike PBO, which is only a synergist, both active ingredients are insecticides that can individually kill a mosquito. The combination of two insecticides can potentially decrease the emergence of resistance, as mosquitoes resistant to one insecticide may still be susceptible to the other. There are currently two dual-insecticide ITNs that have received WHO PQ approval, though neither has received a WHO policy recommendation: the Interceptor G2 and Royal Guard. The Interceptor G2 has a combination of alphacypermethrin, a pyrethroid, and chlorfenapyr, a slower-acting insecticide that targets energy production in the mitochondria. The Royal Guard has a combination of alphacypermethrin and pyriproxyfen, an insect growth regulator that reduces fecundity of female mosquitoes and may also reduce their blood feeding and longevity.

Although the Interceptor G2 and the Royal Guard have WHO PQ recommendations as ITNs, there is currently no WHO policy guidance on when these ITNs should be deployed instead of pyrethroid-only nets. The new types of ITNs are expected to be more expensive than pyrethroid-only nets, so targeting their use to the appropriate settings will be crucial for maximizing impact.

In 2019, WHO released and updated (May 2019) its “Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO policy class.”<sup>22</sup> The aim of this protocol is to support the generation of entomological data to inform a decision as to whether a candidate insecticide-treated net product should become part of an existing WHO policy class. An initial set of non-inferiority studies on pyrethroid-PBO nets, planned for 2019, will be used to validate whether the method outlined here serves its intended purpose before a decision will be taken as to whether demonstration of non-inferiority of second-in-class products becomes a standard WHO requirement.

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<sup>22</sup> <https://www.who.int/malaria/publications/atoz/non-inferiority-protocol/en/>

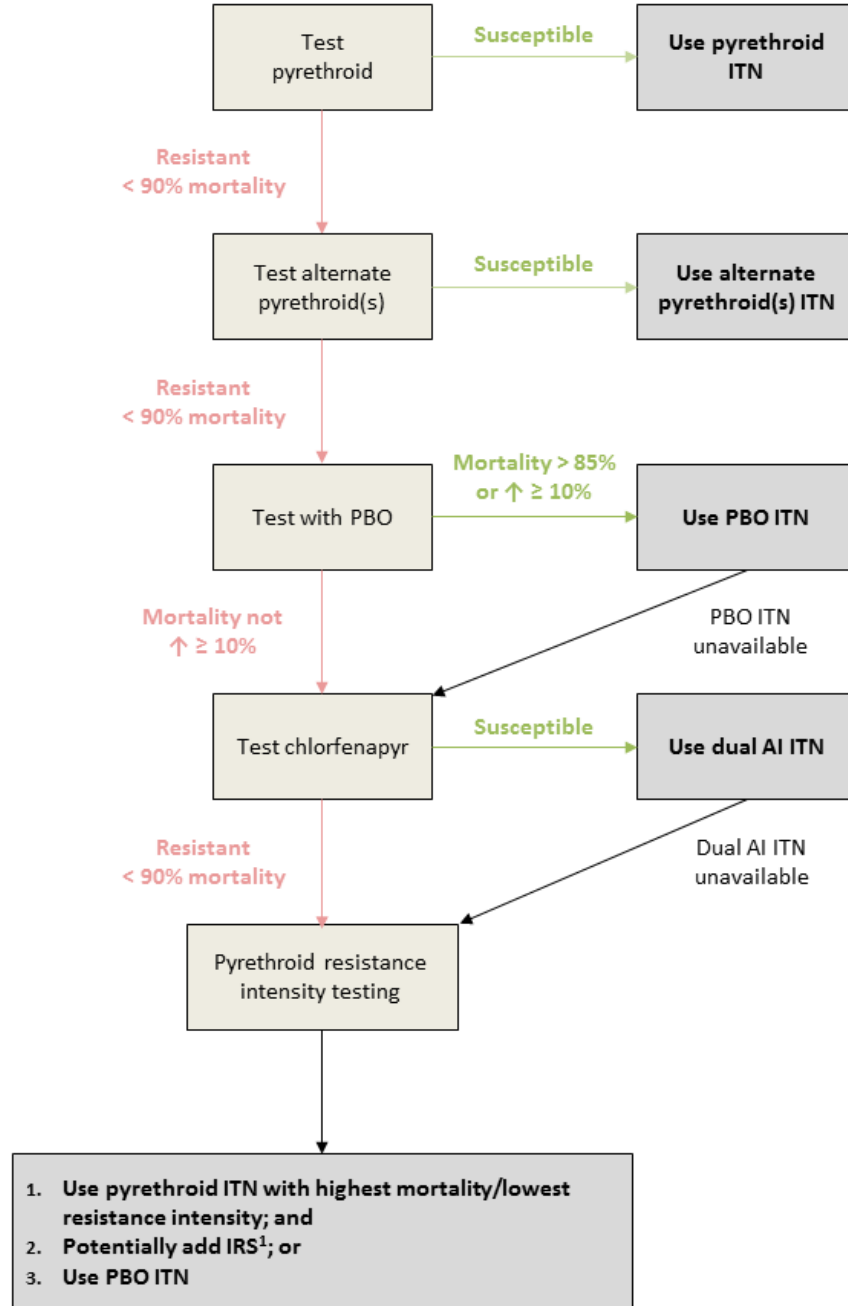
Additionally, a UNITAID and Global Fund catalytic initiative<sup>23</sup> is funding randomized controlled trials and pilot implementation studies to generate evidence for the needed policy recommendation, as well as subsidize procurement of new types of nets. Through a partnership with UNITAID and the Global Fund, the future subsidy will be available for select PMI focus countries which receive approval from HQ to procure new types of ITNs. PMI will also collaborate closely in the evidence generation aspects of this initiative. If NMCPs or country teams are considering procuring new types of ITNs, they should engage with the PMI VMCT team for further guidance.

In order to help teams determine which ITN(s) is most appropriate for a given country context, please refer to the decision tree below.

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<sup>23</sup> <https://unitaid.eu/call-for-proposal/catalyzing-market-introduction-next-generation-long-lasting-insecticidal-nets-llins/#en>

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



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

## ITN Coverage Goal: Universal Coverage of ITNs

When PMI was launched in 2005, most malaria programs and donors targeted ITNs to the most vulnerable groups: pregnant women and children under five years of age. Based on the 2017 WHO recommendations, PMI’s current goal is to help countries reach and maintain universal



coverage of long-lasting ITNs for all individuals living in malaria endemic areas, with a specific target that at least 90% of households with a pregnant woman and/or children under five years of age own at least one ITN. Universal coverage is operationally defined as one ITN for every two individuals, based on evidence from across sub-Saharan Africa that, on average, two individuals occupy each sleeping space.<sup>24</sup>

To achieve and maintain universal ITN coverage, countries should apply a combination of mass free net distribution through campaigns and continuous distribution through multiple channels, in particular through antenatal care (ANC) clinics and the expanded programme on immunization (EPI). Mass campaigns are the only proven cost-effective way to rapidly achieve high and equitable coverage. Complementary continuous distribution channels are also required because coverage gaps can start to appear almost immediately post-campaign due to net deterioration, loss of nets, and population growth.<sup>25</sup>

In countries where insufficient ITNs and donor support to reach and maintain universal coverage exists, PMI should, at a minimum, ensure that routine distribution to children under five years of age and pregnant women remains functional on an ongoing basis. The goal is to ensure that ITN distribution to these biologically vulnerable populations continues uninterrupted while the constraints to achieving universal coverage are addressed.

Quantification for universal coverage, which relies on some form of delivery based on households, has evolved in recent years. To take into account rounding up of net numbers in households with an odd number of inhabitants (e.g., a household with five inhabitants receives three not two ITNs), WHO recommends 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 buffer amount.<sup>26</sup>

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<sup>24</sup> WHO. Achieving and maintaining universal coverage with long-lasting insecticidal nets for malaria control. December 2017. <https://apps.who.int/iris/bitstream/handle/10665/259478/WHO-HTM-GMP-2017.20-eng.pdf?sequence=1>

<sup>25</sup> Ibid.

<sup>26</sup> Ibid.

## ITN Ownership: Key Distribution Channels

### *Mass distribution campaigns to achieve universal coverage*

To rapidly and equitably achieve universal coverage, PMI and many other donors support free-standing, mass distribution campaigns designed to reach every household in malarious areas. These campaigns have proven to be highly successful and have been associated temporally with a drop in child mortality in a number of PMI-supported countries. Mass distribution campaigns are only cost-effective when a majority of ITNs need to be replaced; thus, it is currently recommended that campaigns are conducted every three years, based on projections of ITN longevity. Campaigns usually require logistics and planning expertise as well as time commitments that can strain national program capacities. Research has shown that the key determining factor for a successful campaign is a thorough registration and microplanning process, thus maximizing registration completeness and using a universal coverage allocation strategy are likely to improve campaign outcomes.<sup>27</sup>

PMI builds capacity in countries to manage and implement ITN mass distribution campaigns. In line with the USAID Administrator's priority to foster self-reliance, in PMI focus countries where in-country capacity exists, teams should look first to local partners to lead implementation of mass campaigns. If technical assistance is not available at the country level for campaigns, PMI works with the RBM Partnership to End Malaria Country/Regional Support Partner Committee (CRSPC) to ensure that external technical assistance can be supported. PMI funds will no longer support external TA support (e.g., AMP consultants) for mass campaigns. Therefore, if an NMCP would like to request external TA for an upcoming mass campaign, they should follow the process outlined on the [CRSPC website](#):

- [Country Technical Assistance Application Process](#)
- [CRSPC Country Technical Assistance \(TA\) Request Form](#)

Country teams should inform Lilia Gerberg ([lgerberg@usaid.gov](mailto:lgerberg@usaid.gov)) about requests to RBM for TA.

As countries plan for their next mass campaign, they have sought guidance from WHO on how to account for current (existing) net ownership at the household level when preparing the quantification for the next mass distribution campaign. Experience shows that “top up campaigns” (i.e., selectively replacing older nets, rather than universally providing new nets) are logistically challenging, costly, time-consuming and invariably inaccurate in practice, especially when net access is low. Therefore, WHO/Global Malaria Program recommends that countries do

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<sup>27</sup> Zegers de Beyl, Celine. Multi-country comparison of delivery strategies for mass campaigns to achieve universal coverage with insecticide-treated nets: what works best? 2016. *Malaria Journal* 15: 58. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4740992/>

not plan for periodic “top-up campaigns” until a country establishes a robust continuous distribution system where 40% or more of the target population have long-lasting ITNs that are less than two years old. PMI does not allow PMI resources to support top-up campaigns at the present time.

Further information on mass campaigns, including a comprehensive toolkit are available through the Alliance for Malaria Prevention (AMP) website at:

<http://allianceformalariaprevention.com/amp-tools/amp-toolkit/>.

### *Continuous distribution channels to maintain universal coverage*

Following even highly effective mass campaigns, a supply of nets to the community is needed almost immediately to address: (a) those missed by the campaign; (b) new entries to the population by birth or immigration; and (c) the physical deterioration of existing nets. The maximum population reached for each of the continuous distribution approaches described below falls short of maintaining ITN coverage at levels that will provide community protection. Therefore, a mix of several of the following routine distribution approaches will 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. Country teams interested in accelerating or exploring the potential for any continuous distribution approaches adapted to specific contexts can contact the PMI Headquarters ITN Team for guidance.

To help NMCPs and PMI teams determine the best mix of distribution channels, PMI funded the development of NetCALC, an Excel-based modeling tool that is designed to model several scenarios of continuous distribution approaches based on the countries existing ITN coverage data and situation. It also helps provide quantification of ITNs for each channel or approach. It is flexible and has several variables that work towards the best situation for a country to sustain high ITN coverage. Additional information, an on-line training module, and the model itself can all be accessed and downloaded at: <http://www.k4health.org/toolkits/continuous-distribution-malaria/netcalc-tool-planning-cd>.

The ITN continuous distribution eToolkit is a helpful resource for planners who need to review a variety of 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.

The PMI VectorWorks project conducted a meta-analysis of costs of the following distribution channels in 2017: mass campaigns, ANC, EPI, school-based, and community-based. The analysis found that in terms of cost-effectiveness, conducting universal coverage campaigns

every three years plus ongoing ANC/EPI distribution is equally cost-effective as full-scale school or community distribution plus ongoing ANC/EPI, in terms of cases averted. Conducting mass campaigns every three years with ongoing ANC/EPI and with school distribution in non-campaign years is more costly, but may provide additional health benefits in historically high transmission settings (EIR >32).<sup>28</sup>

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

Routine distribution of ITNs through public-sector<sup>29</sup> ANC and EPI vaccination clinics has the advantage of targeting the most vulnerable groups in the population: pregnant women and children less than five years of age. There is some evidence that these channels also serve as an incentive and thereby increase clinic attendance. In most countries the nets are given free-of-charge, but may also be sold at highly subsidized prices.

Distribution through ANC and EPI at public health clinics will reach a maximum of only about 5% of households, if the annual national cohort of pregnant women attend ANCs and all children attend EPI clinics and receive their scheduled vaccinations. Thus, routine distribution of ITNs through these two channels is not sufficient alone to maintain ownership levels achieved through mass distribution campaigns.

### *School-based distribution channels*

Countries are increasingly considering schools as a channel for delivery of long-lasting ITNs, as this channel has the capacity to put 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) operates in 14 regions, and has been shown to maintain coverage over time.<sup>30</sup> Some smaller school-based distribution pilots have also been conducted (e.g., Guinea, Mozambique). School-based distribution should be considered a viable channel in certain circumstances (including high gross school attendance rate and strong commitment of local health and education officials) to help countries maintain

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<sup>28</sup> Costs and Cost-effectiveness of LLIN distribution strategies in sub-Saharan Africa. [https://endmalaria.org/sites/default/files/Josh-Yukich\\_Cost-effectiveness-of-LLIN-distribution.pdf](https://endmalaria.org/sites/default/files/Josh-Yukich_Cost-effectiveness-of-LLIN-distribution.pdf) [publication forthcoming]

<sup>29</sup> The range of facilities considered to be part of the public sector will differ by country, but includes government-managed facilities that provide public health services specifically for the general population, as well as public health organizations (typically non-government and faith-based) that provide public health services for the general population on behalf of the government. In some countries, partnerships with private sector facilities may also be considered part of the public health sector, if they provide specific services in accordance with public sector policies (e.g., malaria prevention and curative services for free) and on behalf of the government.

<sup>30</sup> Shabbir Lalji et al. School Distribution as Keep-Up Strategy to Maintain Universal Coverage of Long-Lasting Insecticidal Nets: Implementation and Results of a Program in Southern Tanzania. *Global Health: Science and Practice* June 2016. <http://www.ghspjournal.org/content/4/2/251>

universal coverage. PMI-funded pilots in Ghana and Nigeria have shown that school-based distribution significantly increases household ownership of at least one ITN without oversupply. Specifically in Nigeria, adding schools to ongoing ANC distributions not only sustained but increased ITN ownership in the study area. School-based distributions have a high level of flexibility, by adding or subtracting classes, based on need. A school-based channel requires a large amount of coordination between the ministries of health and education (among others) and may not be appropriate or feasible in some countries or sub-regions. In addition, PMI does not recommend conducting both school and community-based distribution due to potential oversupply (see below).

### *Community-based distribution channels*

Community-based distribution makes ITNs available on a continuous basis to community members who meet certain established criteria. Eligible people may approach community agents who distribute 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. This distribution channel may have a useful role to play as part of an overall strategy to maintain ITN coverage levels. Resources specific to this channel can be found at the [ITN continuous distribution eToolkit](#). As mentioned above, community-based distribution is appropriate only if it can increase coverage without too much overlap with other continuous distribution models. Where school-based distribution is already implemented, community-based distribution may not be needed, and may be too much of an additional administrative and management burden.

### *Social marketing of ITNs*

Social marketing of ITNs builds on a long history that has been used for the promotion and sale of oral rehydration salts, contraceptives, condoms, and other health commodities. This approach has the advantage that it responds to demand for the product; when the ITNs are generally subsidized, they reach a much larger population than full price nets in the commercial sector. Traditional social marketing programs:

- Usually involve development and promotion of a special brand, sold at a subsidized price
- Often require development and maintenance of a parallel system for distribution of the subsidized commodity to commercial outlets and other points of sale (e.g., health facilities)
- Share costs among the public sector, donors, and consumers, but are still dependent on public sector and/or donor financing

- Are more frequently focused on urban rather than rural settings and are limited to those who can afford a highly subsidized ITN, meaning equity is a concern
- May fill a partial need in a multi-pronged distribution strategy

### Commercial sales of ITNs

Commercial sales of ITNs can contribute to the overall level of ITN coverage. This approach makes nets available to those who seek a greater choice in size, shape and color, and who can afford to pay the higher price. This method has a limited coverage (i.e., largely in urban areas), as full market prices are usually unaffordable to those at greatest risk in rural areas where vendor sites (kiosks, shops, pharmacies) and ability to pay tend to be more limited.

### Other potential continuous distribution approaches

Other potential continuous approaches may be needed to maintain high coverage and to keep ITNs in targeted communities include:

- Child Health Days, and possibly other periodic health facility or community activities to inject nets into the community.
- A private-sector E-coupon program. The ITN subsidies (paid for by donors and participating private sector companies) are provided to designated target groups (e.g., employees) through SMS messages. E-coupons may support long-term sustainability of distribution by relying on efficient private-sector supply chains, managing multiple sources of funding, and providing reliable and real-time operational information.

Regardless of the channel(s) chosen, each has risks that can threaten its effectiveness toward maintaining universal coverage. All channels require appropriate monitoring and supervision to ensure that the ITNs are responsibly distributed to the intended recipients or households and that abuse of the channels is prevented from happening or identified quickly if they do occur.

Resources for organizing and designing continuous distribution efforts can be found on the Continuous Distribution Toolkit at: <http://www.continuousdistribution.org>.

Once continuous distribution channels are established, sub-national free distribution campaigns may still be needed periodically in areas where continuous distribution approaches fall short, when funding is limited, or other channels are not feasible.

## **ITN Use: Ensuring Correct and Consistent Use**

### *ITN indicators measure access to an ITN*

In 2013, the RBM Monitoring and Evaluation Reference Group adopted four indicators for ITN ownership and use to better reflect the universal coverage strategy. The following indicators (the

supplemental indicator is optional) are currently included in all household surveys (MIS and DHS):<sup>31</sup>

- 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 (supplemental indicator)

These indicators enable countries to measure the proportion of nets available in each household that are used the night before the survey, thus distinguishing non-use related to access to an ITN from that linked to behavior. PMI has funded a 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 how ITN use in their country may be linked to access, or to other behaviors.<sup>32</sup> This report will continue to be updated as datasets from new surveys becomes available.

The two household-level indicators—one representing minimal coverage, the other only ‘universal’ coverage—provide an incomplete picture of personal protection and the success of an ITN distribution programme. Thus, population access to ITNs—which is based on people as the unit of analysis—should be considered as the primary indicator of ITN coverage when assessing the success of ITN distributions.<sup>33</sup>

### *Access to ITNs*

The persistent and widespread gap between ownership and use has been a major concern in the malaria community for several years. However, studies as early as 2009<sup>34</sup> demonstrated that the greatest determinant of use of an ITN was ownership. More recent studies supported by PMI have refined that finding and more clearly demonstrated that the persistent and often large gap between ownership and use is frequently due to too few ITNs in the households rather than individual choice to not use an ITN.<sup>35,36</sup> A PMI-supported study, based on reanalysis of the 2010 Nigeria MIS data, revealed that the relatively large, national-level gap between ownership of at

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<sup>31</sup> MEASURE Evaluation, MEASURE DHS, President’s Malaria Initiative, Roll Back Malaria Partnership, UNICEF, World Health Organization. Household survey indicators for malaria control. 2013. <https://www.measureevaluation.org/resources/publications/ms-13-78>

<sup>32</sup> ITN Access and Use: <http://www.vector-works.org/resources/itn-access-and-use/>

<sup>33</sup> Assessing whether universal coverage with insecticide-treated nets has been achieved: is the right indicator being used? 2018. Hannah Koenker et al. *Malaria Journal*, 17: 355. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6180430/>

<sup>34</sup> Assessment of insecticide-treated bednet use among children and pregnant women across 15 countries using standardized national surveys. Eisele TP, et al., 2009. *Am Journal Trop Med Hyg*, 80:209-214

<sup>35</sup> Universal coverage with insecticide-treated nets-applying the revised indicators for ownership and use to the Nigeria 2010 malaria indicator survey data. 2013. Kilian A, et al., *Malaria Jour*, 12:314.

<sup>36</sup> Recalculating the net use gap: a multi-country comparison of ITN use versus ITN access. 2014. Koenker,H and Kilian, A, *PLoS ONE*, 21;9(5):e97496.

least one ITN (42%) and net use the previous night (24%)<sup>37</sup> masked very divergent regional characteristics. The study found distinct differences between the three Northern and the three Southern geopolitical zones.<sup>38</sup> A key difference was that among people with access to a net within their household, net use was 89% in the North versus only 64% in the South. This clearly shows that for the Northern zone, low availability of nets may largely explain the significant use gap, and that use will improve with an increase in ITN availability. In the Southern zone, on the other hand, a significant gap between net access and use may indicate that a sizable proportion of the population do not use ITNs even when they are available. In this case, promoting behavior change along with increasing ITN availability may help improve net use rates.

Social and behavior change (SBC) for increased net usage and systems for sustained availability of ITNs after campaigns is critical. Studies confirm that SBC interventions are effective at increasing use of ITNs among targeted populations. The *Malaria SBCC Indicator Reference Guide: Second Edition (2017)*<sup>39</sup> is a resource to strengthen the evaluation of the effectiveness of malaria SBC interventions and to measure levels of behavior change for malaria prevention and case management at the country level.

### *Hang-up campaigns*

Many PMI-supported countries have supported net hang-up campaigns in the aftermath of mass distribution campaigns to promote correct and consistent use of ITNs, where volunteers go to each house and help to physically hang up all of the campaign nets (sometimes also supplying nails and string). Costs can range from \$1 to \$1.50 per net hung. To validate PMI's investment in this activity, PMI conducted a study in Uganda to understand the effectiveness of post-campaign, door-to-door hang-up and communication interventions to increase long-lasting insecticide-treated bed net utilization.<sup>40</sup> The results showed no statistical effect of either the routine post campaign visit or the intensive three-month visit or an additional visit at six months in the study setting. While the generalization of these results is limited to areas of similar contexts, the findings were similar to other study results in African settings. **Therefore, PMI does not routinely prioritize support for hang-up activities, and will only support such activities as part of mass campaigns on an exceptional basis with strong justification.** Community-wide SBC efforts to promote correct and consistent use of ITNs should be prioritized over any type of door-to-door campaign to educate the population on these issues.

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<sup>37</sup> Nigeria Malaria Indicator Survey 2010.

<sup>38</sup> Universal coverage with insecticide-treated nets-applying the revised indicators for ownership and use to the Nigeria 2010 malaria indicator survey data. 2013. Kilian A, et al., *Malaria Jour*, 12:314.

<sup>39</sup> <http://www.rollbackmalaria.org/files/files/resources/Malaria-BCC-Indicators-Reference-Guide.pdf>

<sup>40</sup> Kilian A, Balayo C, Feldman M, Koenker H, Lokko K, Ashton RA, et al. (2015) The Effect of Single or Repeated Home Visits on the Hanging and Use of Insecticide-Treated Mosquito Nets following a Mass Distribution Campaign - A Cluster Randomized, Controlled Trial. *PLoS ONE* 10(3): e0119078. doi:10.1371/journal.pone.0119078



## Cost of ITNs

Cost assumptions for FY 2020 ITN procurements are provided in the **Commodity Procurement** chapter. The costs provided there include the purchase price of the net itself, freight (which includes insurance and may include in-country delivery from port to destination), and quality assurance. However, the related procurement costs do not include warehousing. There is great variability across countries as to what the government provides as opposed to what PMI supports via partners (e.g., in some countries warehousing is provided by the government and the partner is only responsible for distribution costs, whereas in others the partner is responsible for both warehousing and in-country distribution). Therefore, warehousing -- whether temporary for mass campaigns or long-term for routine distribution -- needs to be factored into the “additional costs.”

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

For continuous distribution efforts, countries should budget adequate funds to support logistics of distributing the nets to the districts and points of service on an ongoing/periodic basis, appropriate communication efforts, and appropriate supervision and monitoring efforts. The costs for delivery of ITNs provided free of charge through continuous distribution through schools, communities, or health facilities ranged from \$0.77 to \$9.94 (median about \$2.72).<sup>41</sup>

## Care of ITNs

Endemic countries and international partners are looking for ways to maintain the average expected life of ITNs, which could result in large savings over time. One possible way to extend the life of ITNs is to improve the household’s level of care of ITNs. PMI has funded operational research in Nigeria and Uganda to understand the knowledge, attitudes, beliefs, and practices that motivate or impede net care and repair behaviors used findings to test the effectiveness of a behavior change communication intervention. Based on these results,<sup>42,43</sup> PMI will not support

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<sup>41</sup> Wisniewski et al. Systematic review and meta-analysis of the cost and cost-effectiveness of distributing insecticide-treated nets for the prevention of malaria. *Acta Tropica* 2019 (in review).

<sup>42</sup> Koenker H, Kilian A, Hunter G. Impact of a Behaviour Change Intervention on Long-Lasting Insecticidal Net Care and Repair Behaviour and Net Condition in Nasarawa State, Nigeria. *Malaria J*, 2015, 14:18. Accessed at: <http://www.malariajournal.com/content/14/1/18>

repair activities (e.g., distribution of ITN repair kits, social mobilization promoting ITN repair efforts, etc.).

PMI will support SBC activities focused on comprehensive ITN care and consistent use (not repair) messages, with primary emphasis on promoting preventive behaviors that protect the net from damage, such as folding or tying the net up every day, keeping children from playing near the net, washing correctly, avoiding storing food or crops in the same room, and storing the net safely when not in use. SBC should promote improving overall care of ITNs at the household level and delaying the development of holes for as long as possible.

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

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

### *Disposal*

It is estimated that 1 billion ITNs were distributed in Africa since 2000. With an estimated life span of three years, it is likely that many ITNs are expired and are no longer viable. There are risks associated with so many nets now in the environment, and the potential environmental impact related to the disposal of these nets has been raised by the WHO and other stakeholders.

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.

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<sup>43</sup> Helinski M, Namaral G, Koenker H, et al. Impact of a Behaviour Change Communication Programme on Net Durability in Eastern Uganda, *Malaria J*, 2015, 14:366. Accessed at: <http://www.malariajournal.com/content/14/1/366>

- Old ITNs should only be collected where there is assurance that: i) communities are not left uncovered, i.e. new ITNs are distributed to replace old ones; and ii) there is a suitable and sustainable plan in place for safe disposal of the collected material.
- Collecting old ITNs should not divert effort from core duties, including maintaining universal coverage.
- If ITNs and packaging are collected, the best option is high-temperature incineration, not burning in open air. In the absence of appropriate facilities, they should be buried away from water sources and preferably in non-permeable soil.

WHO found that recycling and incineration were not practical or cost-effective in most settings at this time, confirming the results from PMI's experience in piloting a recycling effort in Madagascar in 2010.<sup>44</sup>

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

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

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<sup>44</sup> In 2010, USAID sponsored a recycling pilot in Madagascar. This looked at several key factors including recovery, transporting, and parameters for converting expired ITNs into a viable alternative product. It was determined that the technology required for this process was not available in Madagascar, and that the cost to ship ITNs back to the US for processing was prohibitively high. Outside of this one recycling pilot, there is no evidence that large quantities of ITNs have ever been collected for disposal, nor has evidence been presented that there is a positive outcome in collecting ITNs for disposal. Most expired ITNs remain at the site and are either repurposed or disposed of at a household level. Please see: Nelson, Michelle, Ralph Rack, Chris Warren, Gilles Rebour, Zachary Clarke, and Avotiana Rakotomanga. 2011. *LLIN Recycling Pilot project, Report on Phase II in Madagascar*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3. AND Nelson, Michelle, and Ralph Rack. 2012. *Madagascar: LLIN Recycling Pilot Project, Report on Phase III*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 7. Both reports can be downloaded at: [http://deliver.jsi.com/dhome/search?p\\_search\\_tok=madagascar+recycling&btnG=search](http://deliver.jsi.com/dhome/search?p_search_tok=madagascar+recycling&btnG=search)

plan for what happens to old ITNs and packing materials in the environment in collaboration with other relevant partners.

## *Misuse*

Misuse is defined as the use of a viable ITN for purposes other than its intended use as a bednet. Misuse of ITNs is not acceptable under any circumstances and not only defeats the public health purpose of providing protection from malaria, but can also have negative environmental outcomes. The most ecologically damaging use of ITNs is for fishing. Pyrethroids can kill fish, especially young fish, aquatic crustaceans, and insects when leached from a viable ITN being used for fishing. The fine mesh of treated or untreated mosquito nets may also cause ecological damage by physically removing many small aquatic animals from an area. This is less of an issue in larger bodies of water but can be a significant problem in small streams and ponds. There are no other known misuses of viable ITNs that pose serious environmental risks. Evidence in the literature indicates that in isolated cases, usually fishing communities, misuse of ITNs can be a problem and efforts should be made to address these situations. However, there is “very little evidence to support claims of widespread misuse across Africa.”<sup>45,46</sup>

## *Repurposing*

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

In 2018, RBM issued a *Consensus Statement on Repurposing ITNs: Applications for BCC Messaging and Actions at the Country Level*<sup>47</sup> to provide National Malaria Control/Elimination Programs (NMCPs) and implementing partners with clear recommendations and key messages on three categories of repurposing: beneficial repurposing, neutral repurposing, and misuse:

- **Beneficial repurposing** is the use of inactive ITNs for purposes other than for sleeping under to protect against malaria infection. It is considered beneficial because the ITN material continues to act as a barrier against mosquitos. Examples of

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<sup>45</sup> Eisele TP, Thwing J, Keating J. Claims about the Misuse of Insecticide-Treated Mosquito Nets: Are These Evidenced Based? 2011, Plos Med 8(4): E1001019.DOI:10.1371/journal.pmed.1001019

<sup>46</sup> Koenker, H, et al, “What happens to lost nets: a multi-country analysis of reasons for LLIN attrition using 14 household surveys in four countries” 2014, Malaria Journal 13(464) DOI: 10.1186/1475-2875-13-464

<sup>47</sup> <https://endmalaria.org/sites/default/files/Consensus%20Statement%20on%20Repurposing%20ITNs.pdf>

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

## Durability Monitoring

### *Introduction*

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

Similar to monitoring of drug efficacy and insecticide sensitivity, ITN monitoring must compromise between cost and optimal sampling. The diversity of ITN types, environmental circumstances, and cultural practices make exhaustive sampling impractical; however, it is possible and cost-effective to obtain representative data on the major types of ITN distributed. This section provides guidance on how monitoring can be done. It also aims to provide a framework to decide whether monitoring should be carried out and under what circumstances it might be terminated. Programmatic context drives the decision making process; it does not matter whether PMI, the Global Fund, or other funds have been used to purchase the nets.

ITN monitoring measures the effect of normal daily use on four outcomes: (1) **attrition** (survivorship), as measured by the loss of nets from households; (2) **physical durability**, as measured by the number and size of holes in the net; (3) **insecticide effectiveness**, as measured directly but imprecisely by bioassay; and (4) **insecticide content analysis**, as measured accurately by chromatography. These are best monitored in a prospective design linked to a mass

ITN distribution campaign. In the following, we provide a decision matrix for deciding whether to carry out ITN monitoring and provide guidance for sample sizes for each outcome.

All PMI-funded durability monitoring activities should follow the study protocols, questionnaires, and other tools available via <https://www.durabilitymonitoring.org/>

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

Factors affecting whether ITN durability monitoring might be undertaken include:

1. **Stage of malaria control.** ITN monitoring is most valuable for countries whose programs are in control phase and distribute large of numbers of ITNs. It is less useful for a program approaching elimination which distributes fewer numbers of ITNs.
2. **Size and diversity of the country.** The larger the country and the more diverse it is culturally and environmentally, the more useful ITN monitoring is likely to be. A small country with limited diversity might carry out monitoring in one site, while a larger country with greater environmental or cultural diversity might monitor ITNs at two sites. Monitoring at more than two sites is not recommended.
3. **Numbers of types of ITN distributed.** Programs that rely heavily on one brand or type of ITN might carry out durability monitoring on that brand only, while a country distributing large numbers of several types of nets might wish to carry out durability monitoring on the two major types of nets used. Monitoring more than two net types concurrently is not recommended. If a country team proposes more than two sites, justification must be provided to the HQ ITN team as to how these data will be used and to ensure that other elements of the overall PMI portfolio are adequately funded.
4. **Availability of data.** Countries with no data should consider carrying out ITN monitoring. Programs that distribute nets that have not previously been subjected to routine monitoring in other countries should also be given priority, especially new types of ITNs for which no durability data yet exist. Countries with data available on the durability of specific brands of nets distributed in the country should discuss with NMCP and partners whether further monitoring on those brands continues to be a priority.
5. **Programmatic context.** Programs have multiple priorities. It is possible that other priorities such as diagnosis, treatment, or surveillance might take precedence, depending upon country context.

Clearly, the above factors are best weighed by PMI country teams in consultation with NMCPs, with a view towards extracting maximally useful data with the least expenditure. Some extreme cases have clear outcomes. A small country with existing data on the type or types of ITN to be

distributed in the future can discontinue monitoring. A country that is distributing small numbers of ITNs in the context of malaria elimination has no urgent need to carry out ITN monitoring, even if data on ITN durability are unavailable. In contrast, a large country distributing large numbers of several types of ITN with no country-specific data should make ITN monitoring a priority. A country introducing a new type of ITN into its program should also begin monitoring its durability. Most countries will fall between these extremes and should exercise judgement in deciding upon whether or not to initiate monitoring.

### *If ITN monitoring is done, which outcomes should be measured and with what sample size?*

ITN durability monitoring consists of four outcomes: attrition, physical integrity, insecticidal activity and insecticide content. Depending upon the country context, it may be necessary to limit which outcomes are measured. At a minimum, all countries should have the capacity to measure attrition and physical integrity. These outcomes do not require any special equipment or expertise. Further, recent evaluations suggest that these factors may be the most important limiting factor in ITN durability. Attrition and physical durability can be reasonably measured in a cohort sample of 250 marked nets followed longitudinally and examined yearly for three years. With this sample size, using 15 clusters of 10 households each where all nets are marked in selected households, countries will be able to detect approximately 20% variation in performance among products over a three year period, equivalent to approximately plus/minus 6-7 months of median net lifespan.

Insecticidal activity is measured by exposing ITNs to susceptible mosquitoes in WHO cones. Because the purpose of the activity is to measure insecticidal activity, any susceptible species of mosquito may be used for the bioassay. This activity requires specialized facilities and staff, in particular an insectary with a susceptible colony of mosquitoes and lab staff with the ability to consistently generate large numbers of mosquitoes of uniform quality required for bioassays. If an insectary is not available, net samples may be sent to an outside laboratory for analysis. Measurement of insecticidal activity at baseline, 12 and 24 months should be done on nets from outside the main cohort of ITNs being monitored and at 36 months from the main cohort, whereby 30 nets are taken from the field for laboratory testing each year for three years. Nets collected at the baseline, 12 and 24 months may be identified through one of two methodologies, either: a) random selection from outside the study cohort; or b) tagging a separate bioassay net cohort at baseline. Each methodology has pros and cons and should be selected based on what is most appropriate within the country specific context. The nets taken from the field will need to be replaced by new nets.

Whereas previously, PMI had not funded baseline measurement of insecticidal content via durability monitoring, given that ITNs undergo pre-shipment testing, given recent experience, PMI now recommends bioassay and chemical content testing even at the earliest timepoint.

Furthermore, it is recommended to retain 30 nets before distribution for confirmation in the event that unexpected results are obtained. At subsequent follow ups, insecticidal content testing may be done on samples of the same 30 nets taken from the field for bioassays. If bioassays are being performed, the marginal cost of performing insecticidal content analysis is determined by the cost of the laboratory analysis; for 30 samples this cost will range from \$4,500–\$10,500. Such analysis should be given priority where there are no existing data or where new compounds or new net technologies are in use. If bioassay data demonstrate a loss of effectiveness, PMI should carry out chemical content testing.

The measurement of insecticidal content should be done at baseline. Measurement of insecticide content may be done on subsequent follow ups but should be considered a low priority unless the bioassays indicate reasons for concern (e.g., low mortality). Chemical content testing should not be done independently of bioassays. Determination of insecticidal content can be used to confirm the bioassays and estimate insecticide retention rates across different settings and in different ITN products. However, measurement of insecticidal content requires highly specialized capacity that is likely limited or absent in nearly all PMI-supported countries. Therefore, this must be done either at CDC or at a WHO collaborating center where the cost of analysis is approximately \$150-\$350 per sample. Furthermore, in some cases, there is a poor correlation between insecticidal content and insecticidal activity, particularly for some ITNs made of polyethylene with insecticide directly incorporated into the fiber. We do not generally recommend carrying out content testing for nets types which incorporate insecticide in solution in the net fiber.

### *How to monitor the insecticidal content of PBO and Dual AI nets?*

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., piperonyl butoxide), insecticides with relatively well-understood properties (ie. deltamethrin), and/or new insecticides for adult mosquito vector control, which may have different modes of action (i.e., clothianidin, chlorfenapyr, pyriproxyfen). The combination of these active ingredients on the same ITN provides a challenge for evaluation of the efficacy of these products, as one efficacious treatment may “mask” the inefficacy of the other.

For dual AI nets, durability monitoring should include bioassays -- cone bioassays and, where necessary, tunnel tests -- and chemical content testing at all time points. Ideally, bioassays should be done with both a susceptible strain and a resistant strain derived from local mosquito populations. However, given that most countries do not have access to pyrethroid resistant colonies, bioassays should be conducted with a susceptible colony and wild mosquitoes. If net failures are detected, samples could be outsourced to a lab with a resistant colony for confirmation.

PMI encourages countries to develop colonies of local strains that are resistant to pyrethroids, maintained under selection, and routinely characterized so tests can be performed locally. Strains



of resistant mosquitoes must be kept separately from susceptible strains, preferably in separate buildings, but at least in separate rooms, with clear SOPs and access restricted to those trained on SOPs. Furthermore, PMI encourages countries to build capacity in countries to conduct tunnel tests, recognizing that there may be some initial hurdles around training, animal ethics approval, etc.

For specific guidance on monitoring new types of nets, please contact your respective VMCT backstops.

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

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

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

Results of ITN monitoring can be used:

- To determine the median ITN life in a country and understand factors affecting attrition and ITN performance
- To inform improved procurement practices to ensure that ITNs bought provide as optimal performance as can be expected
- To inform countries on how to develop their ITN distribution strategies to ensure nets are available when needed, depending on median life
- To inform countries to develop effective SBC messages on the care of ITNs
- To provide information to WHO/PQ and manufacturers on the durability of different ITNs under different conditions to improve products and their specifications

Durability monitoring results can help PMI identify when an ITN product does not meet acceptable standards for integrity and insecticidal effectiveness. It is NOT powered to identify a

product that is significantly superior in quality as to justify preference for procurement. PMI teams should explain this carefully to NMCP and malaria partners when results are presented. Guidance documents on what levels of ITN attrition, physical damage, and bioefficacy would constitute poor performance, and actions to be taken in response are posted on [www.durabilitymonitoring.org](http://www.durabilitymonitoring.org).

## Frequently Asked Questions for ITNs

### Q1. What is the difference between conventional ITNs and LLINs?

A. Early versions of insecticide-treated nets – conventional ITNs – were dipped post-production (by the end-user) in a pyrethroid insecticide mixture containing ligands to bind the insecticide to the polyester netting. This process produced nets with an effective life of only about three washes, with reapplication (re-dipping) recommended every six to 12 months. With LLINs, pyrethroid insecticides are applied during the manufacturing process, either incorporated into the fibers (polyethylene and polypropylene) or coated on the fibers (polyester). To receive a WHO PQ recommendation, long-lasting ITNs must maintain full protective insecticide levels for a minimum of 20 washes. Given the durability of the netting material under field conditions, LLINs are expected to provide up to three years of protection before needing to be replaced. However, field experience has shown that more often netting material deteriorates before the insecticide in the materials falls below minimum protective levels, and that the average lifetime of LLINs may be considerably less than three years. Washing more frequently than recommended may cause a more rapid loss of insecticide efficacy. Long-lasting ITNs are now the only type of net supported by PMI, and in this guidance document "ITNs" and "LLINs" are used interchangeable unless noted.

### Q2. What is an ITN community effect?

A. Where ITN coverage and use at a community level is sufficiently high, the overall malaria transmission intensity in the community is reduced, resulting in some protection for even those not using nets, referred to as a "community effect." While ITNs offer a degree of personal protection to those sleeping under the net, when ITN coverage rates reach a tipping point in a community, even those residents not sleeping under a net have increased protection from malaria infection. The "community effect" is the result of a reduction in malaria transmission due to reduced mosquito longevity and the lower overall mosquito abundance due to exposure to pyrethroids in ITNs.<sup>48,49,50,51,52,53,54,55</sup>

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<sup>48</sup> Hawley WA, Phillips-Howard PA, ter Kuile FO, et al. Community-wide effects of permethrin-treated bed nets on child mortality and malaria morbidity in western Kenya. *Am J Trop Med Hyg.* 2003 Apr;68(4 Suppl):168-73.

<sup>49</sup> Killeen GF, Smith TA, Ferguson HM, et al. Preventing childhood malaria in Africa by protecting adults from mosquitoes with insecticide-treated net. *PLoS Medicine* (2007) accessed at: <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040229>

The PMI goal for coverage is 85%, but in certain ecological situations (e.g., where vectors prefer to feed indoors on humans and there are few alternate hosts available), a community effect may be achieved when more than half of the people (all age groups) in the community use an ITN every night.

### **Q3. What are the side effects of insecticides used on ITNs?**

A. Pyrethroids are the only insecticides currently available for use on mosquito nets due to their extremely low human toxicity (i.e., they are safe enough that a baby sucking on a net would not be harmed). 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.

### **Q4. What are the environmental procedures and assessments that need to take place in order for ITNs to be procured and distributed with PMI support?**

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

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<sup>50</sup> Gimmig J, Vulule J, Lo T, et al. Impact of permethrin-treated bed nets on entomologic indices in an area of intense year-round malaria transmission. *The American Journal of Tropical Medicine and Hygiene*.2003;68:16–22

<sup>51</sup> Ilboudo-Sanogo, N. Cuzin-Ouattara, D. A. Diallo, S. N. Cousens, F. Esposito, A. Habluetzel, S. Sanon, A. P. Ouédraogo Insecticide-treated materials, mosquito adaptation and mass effect: entomological observations after five years of vector control in Burkina Faso. *Trans R Soc Trop Med Hyg*. 2001 Jul-Aug; 95(4): 353–360.

<sup>52</sup> Indome, F., Smith, T., Impact of spatial distribution of permethrin-impregnated bed nets on child mortality in rural northern Ghana. *American Journal of Tropical Medicine and Hygiene*. 1998 Jul;59(1):80-5.

<sup>53</sup> Howard SC, Omumbo J, Nevill C, Some ES, Donnelly CA, Snow RW. Evidence for a mass community effect of insecticide-treated bednets on the incidence of malaria on the Kenyan coast. *Trans R Soc Trop Med Hyg*. 2000 Jul-Aug;94(4):357-60.

<sup>54</sup> Maxwell, C. A., Msuya, E., Sudi, M., Njunwa, K. J., Carneiro, I. A. and Curtis, C. F. (2002), Effect of community-wide use of insecticide-treated nets for 3–4 years on malarial morbidity in Tanzania. *Tropical Medicine & International Health*, 7: 1003–1008.

<sup>55</sup> Magesa SM, Wilkes TJ, Mnzava AEP et al. (1991) Trial of pyrethroid impregnated bednets in an area of Tanzania holoendemic for malaria vector population. Part 2. Effects on the malaria vector population. *Acta Tropica* 49, 97–108.

contamination, and SBC on appropriate use during distribution efforts. The current, full PEA can be downloaded at:

<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>

**Q5. Can PMI support ITN distribution in emergencies and other special circumstances?**

A. Perhaps. From time to time, PMI teams may be approached to support procuring ITNs for separate, targeted distribution rather than as part of universal coverage campaigns or routine distributions as programmed in the MOPs, or that are scheduled in national ITN strategic plans. Examples include distribution to refugees, the military, communities affected by outbreaks such as Ebola, and other special populations. In addition, NMCPs and partners may express interest in geographically-focused campaigns that integrate ITN distribution with those of vaccinations and other services. All have substantial logistical, funding, policy and strategic implications that could impact – positively or adversely – attaining both NMCP and PMI objectives. The PMI Headquarters ITN Team is available to advise on these and other special circumstances that may arise.

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# INDOOR RESIDUAL SPRAYING

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

**New Insecticides:** Over the past two years, two new IRS insecticides have received WHO PQ listing and are now available for use in IRS programs: Sumitomo's SumiShield (clothianidin) and Bayer's Fludora Fusion (clothianidin+deltamethrin). Clothianidin is repurposed from the agriculture industry, and is a slower-acting insecticide from the neonicotinoid class with a different mode of action than other IRS insecticides. Both new products are expected to be long-lasting alternatives to pirimiphos-methyl CS and should be considered as part of a country's insecticide rotation strategy. All countries considering use of these new products should be conducting resistance testing to ensure full susceptibility of the insecticide prior to its use (see **Entomological Monitoring** chapter).

**NgenIRS Project:** The UNITAID-funded Next Generation IRS (NgenIRS) project is ending in December 2019, and thus there should no longer be references to this project in the FY2020 MOPs. As part of the project, two-year price caps have been established with the three main manufacturers of IRS insecticides to help maintain the reduced price of next generation insecticides over the longer term (see details below).

**IRS Withdrawal:** The majority of PMI countries with IRS programs have withdrawn IRS from a given area at one point in time for a variety of reasons. Due to increased questions from the field on the settings under which IRS can be withdrawn and impact of withdrawing IRS, we have expanded this section of our guidance (see details below).

## **Introduction**

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

Successful IRS depends on the use of an insecticide that kills the local malaria vector(s) and the quality of spraying. Unfortunately, IRS successes are now being jeopardized by the spread and intensification of insecticide resistance. According to WHO, mosquito resistance to at least one class of insecticides has been reported from 68 countries with ongoing malaria transmission.

PMI's own entomological data shows evidence of insecticide resistance to one or more classes of insecticides in all PMI-supported countries in Africa. While the majority of PMI-supported countries relied on pyrethroids for IRS in the early years of PMI, because of documented pyrethroid resistance, no PMI-supported IRS programs have used pyrethroids since 2015.

## UNITAID-Funded NgenIRS Project

In an effort to mitigate insecticide resistance, PMI has been partnering with the Innovative Vector Control Consortium, the Global Fund, Abt Associates, and PATH Malaria Control and Elimination Partnership in Africa, on the UNITAID-funded Next Generation Indoor Residual Spraying (NgenIRS) Project, which is currently expected to end in December of 2019. The overall aim of NgenIRS is to accelerate and expand access to and adoption of new, third generation IRS formulations (long-lasting non-pyrethroid insecticide formulations). There are multiple IRS formulations eligible for the NgenIRS co-payment support that have a WHO PQ recommendation (Actellic CS, SumiShield, and Fludora Fusion). UNITAID is supporting the NgenIRS Project because it is a market-shaping intervention that aims to grow and stabilize the market for new, third generational IRS formulations. Given the project's expected conclusion in December of 2019, no reference to the NgenIRS project should be made in FY2020 MOPs. As part of the project's long-term market-shaping activities, they negotiated two-year price caps (2020-2021) with the manufacturers of Actellic CS, SumiShield and Fludora Fusion, which are all dependent upon volume and the receipt of timely consolidated forecasts. The price caps range from **\$14 - \$16.50 per unit of insecticide** depending upon the product and volume. For additional cost information, please see the PMI IRS Team.

## Insecticide Selection

The choice of which insecticide class (or compound) to use in a particular setting should be made with expert consultation (PMI Headquarters IRS Team and PMI/CDC Entomologists), implementing partners, and in-country technical working groups during the planning period for spraying and **at least seven months before the spray campaign** to allow adequate time for procurement, delivery, and receipt of insecticide. All decisions about the choice of insecticide should be done in consultation with the NMCP. PMI has specified the following factors that should be considered in the choice of insecticide class: vector resistance, duration of efficacy, and cost. The choice of insecticides that can be used for IRS is limited. Each has its own advantages and disadvantages as outlined in **Table 1**.

Table 1. Advantages and Disadvantages of IRS-Recommended Chemical Classes			
Chemical class	Advantages	Disadvantages	Cost/sachet or sachet equivalent
Pyrethroids	<ul style="list-style-type: none"> <li>• Low toxicity</li> <li>• Low cost</li> <li>• &gt;7 months duration for longer-lasting formulations</li> </ul>	<ul style="list-style-type: none"> <li>• Resistance</li> </ul>	\$2-3
Carbamates	<ul style="list-style-type: none"> <li>• Medium toxicity</li> <li>• Less resistance</li> </ul>	<ul style="list-style-type: none"> <li>• Higher cost</li> <li>• &lt; 4 month duration****</li> </ul>	\$11*
Organo-phosphates**	<ul style="list-style-type: none"> <li>• Less resistance</li> <li>• CS formulation &gt;6 months duration****</li> </ul>	<ul style="list-style-type: none"> <li>• Higher relative toxicity</li> <li>• Higher cost</li> </ul>	\$15-\$16.50
Organochlorines (DDT)***	<ul style="list-style-type: none"> <li>• Low cost</li> <li>• &gt;7 months duration</li> </ul>	<ul style="list-style-type: none"> <li>• Management costs</li> <li>• Resistance</li> <li>• Supply</li> </ul>	\$4-\$6.70
Neonicotinoids**	<ul style="list-style-type: none"> <li>• Less resistance</li> <li>• Residual efficacy up to 10 months</li> </ul>	<ul style="list-style-type: none"> <li>• Higher cost</li> </ul>	\$14-\$15

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

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

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

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

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, leading to cellular death and eventual insect mortality. One member of this class, chlorfenapyr, has been evaluated by the WHO for use on ITNs, and may be evaluated for use in IRS in the future.

The newest IRS insecticide on the market is Fludora Fusion, a combination insecticide containing clothianidin + deltamethrin. Data from Bayer, the manufacturer of Fludora Fusion, show that there is a complementary effect between the two insecticides and the formulation is designed so the mosquito comes into contact with both insecticides at the same time. Results from 19 field trials, including 6 WHO trials, indicate the product is expected to have a long residual life, similar to SumiShield and Actellic CS, and should be considered as part of a country's rotation strategy. Fludora Fusion trial data also indicates it to be effective in areas with deltamethrin resistance; as such, the PMI VMCT does not believe it is necessary to restrict the use of Fludora Fusion in areas with deltamethrin resistance or deltamethrin based ITNs.

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 6 months on cement, mud, and wood surfaces in most countries. PMI began rolling out SumiShield in 7 countries in 2018 and current data indicates a long residual life, ranging from 6 to 8 months. PMI plans to deploy Fludora Fusion in approximately six countries in 2019; as such, residual life data for this product is pending. 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 small number of countries in West Africa and Ethiopia have shown significantly shorter residual life for all insecticides, with approximately 1-2 months residual efficacy for bendiocarb and 2-3 months for pirimiphos-methyl CS.

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



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

The WHO *Global Plan for Insecticide Resistance Management*<sup>56</sup> recommends rotations, mosaics, and mixtures to slow selection of resistant vectors. As there are now multiple, similarly-priced insecticide formulations available for IRS, PMI supports subnational rotation between insecticides with susceptibility, to the greatest extent possible. As a practical option to manage buffer stocks, it may be possible to spray some districts with insecticide A, and others with insecticide B, and switch annually.

### *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.

**PMI strongly supports the phased implementation of insecticide rotations.** The WHO's *Global Plan for Insecticide Resistance Management*<sup>57</sup> recommends that in areas where IRS is the primary form of vector control, the insecticide used should be preemptively rotated between classes. 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. 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, if countries choose to conduct preemptive rotations, the effects of insecticide rotation on insecticide resistance profiles and implementation costs should be closely monitored and evaluated. In addition, country teams should engage PMI Headquarters IRS Team if/when their country counterparts begin to consider pre-emptive rotation of insecticide in order to appropriately consider needed monitoring and support.

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<sup>56</sup> [http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472_eng.pdf)

<sup>57</sup> <http://www.who.int/malaria/publications/atoz/gpirm/en/>

Country teams should engage the PMI Headquarters IRS Team and their entomology backstop to discuss insecticide resistance management plans in light of new products that have recently become available.

## 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* (<http://www.who.int/malaria/publications/atoz/9789241508940/en/>).

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

- Historically, PMI prioritized support for IRS in areas with seasonal malaria, but with longer lasting insecticides available, PMI also supports IRS in perennial transmission settings as a means to rapidly reduce malaria transmission.
- PMI does not support IRS as an epidemic prevention measure in areas that may experience a malaria outbreak, followed by long periods without transmission. PMI also does not support IRS as an epidemic response measure. In most cases, the logistics and lead time for IRS is too long to allow for rapid response, and often epidemics are over before IRS can be implemented.
- PMI does not typically support IRS in urban settings. However, IRS may be justified once local transmission is confirmed with entomological data, if there are unique circumstances (e.g., delayed LLIN distribution, sudden population shift, or hotspot identified) that can justify IRS, and if urban housing conditions allow for anticipated access with high levels of acceptance among urban community dwellers. The PMI Headquarters IRS Team must be consulted in advance of including urban settings within spray targets.
- 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 Headquarters IRS Team should be consulted.

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

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

- 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 Headquarters IRS Team should be consulted to help with these decisions.
- From 2015-2018, PMI conducted operational research in Zambia to assess the effectiveness and cost implications of focal spraying using three different targeting strategies: 1) Geographic concentration (i.e. density of structures), 2) Health facility-based (i.e. highest burden areas based on HMIS), and 3) Ecological (i.e. breeding sites identified by entomological studies). Study results found that ecological targeting was

associated with a 13% reduction in malaria incidence compared to geographic targeting, while health facility targeting was associated with a 35% *increase* in malaria incidence compared to geographic targeting. Given these results and the further study that's needed, countries that have not already initiated focal spraying should not plan to do so given the uncertainties.

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

- IRS should only be implemented as part of a long-term vector control or malaria elimination strategy.
- When new spray areas are being considered, areas of high transmission that require only one spray round per year to cover majority of the transmission season, should be prioritized.
- There is not an appropriate universal threshold that can be used to determine if a country can withdraw IRS (i.e. after 3 years or after the burden is reduced to a certain level). IRS withdrawal is often influenced by political or financial decisions, or the introduction of new interventions (i.e. PBO synergist and dual active ITNs); both the epidemiological and entomological context should be factored in when considering withdrawal.
- If IRS is withdrawn, it should be in the context of a malaria elimination plan or as part of a malaria control program using a “knock-down/keep-down” strategy (i.e., IRS is used to reduce or “knock-down” the malaria burden, and then effective ITNs are used to maintain or “keep-down” the burden), ensuring universal ITN coverage. Ensuring the population is covered with an effective ITN, which in many cases may require next-generation ITNs, is a critical component of any IRS withdrawal strategy. In addition, IRS should only be withdrawn if access to malaria case management has been achieved in that area.
- To date, all PMI countries with IRS programs have withdrawn IRS from one area (i.e. district), and moved to another area, with varying levels of entomological or epidemiological rebound. If IRS will be withdrawn from an area, PMI recommends developing an IRS Exit Strategy with the NMCP, to document various considerations for removing IRS from an area, and incorporating recommendations and suggested partners for implementation. Considerations include: timing of a mass ITN distribution campaign, and the possibility of utilizing continuous distribution channels or new types of ITNs, if appropriate in the former IRS area.
- If IRS is to be withdrawn because of resource constraints or a shift in a country's IRS targeting strategy, countries should ensure clear SBC messaging, high ITN coverage and use, strengthen malaria case detection and response systems, and closely monitor ACT and RDT stocks. It is prudent to expect and plan for an increase in malaria cases following the withdrawal of IRS. Additional commodities may be needed in the former IRS targeted areas, and entomological monitoring should be continued to monitor the

impact of withdrawal on the vector population. If IRS is the main form of vector control in an area, it should continue to be implemented even as transmission drops.

The country team needs to consult with the PMI Headquarters IRS Team 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 2018, in the majority of PMI-supported countries, insecticide costs average 33% of the IRS budget, depending on the insecticide class used. The three largest cost categories were insecticide (32.6 percent of all costs), spray operations (34.8 percent of all costs), and local labor (16.4 percent of all costs), constituting an average of 83.7 percent of all costs. Based on results from 2018 PMI-funded spray campaigns, the average cost per person protected was \$5.82 (range from \$2.82 to \$14.83) and the average cost per structure sprayed was \$21.10 (range \$12.42 to \$36.18). There is considerable variation in the cost of IRS in PMI-supported countries based on factors such as program scale, cost of local labor, etc.

- For FY 2020 MOP planning and beyond, PMI country teams, together with NMCPs, should consider IRS programs in the context of the current resource allocations for vector control interventions from all sources, given the malaria burden, insecticide resistance profile, and actual program expenditures in each country, and make changes in upcoming years where necessary.

#### ***Key Issue 5: Insecticide Resistance: Implications for IRS***

- PMI must continue to support monitoring of insecticide resistance to inform the selection of insecticides for IRS. PMI supports NMCP efforts to compile national insecticide resistance profiles for this purpose. Please refer to the **Entomological Monitoring** chapter for further details.
- Due to the availability of multiple WHO approved classes of insecticides for IRS implementation, IRS is seen as a potential resistance management tool. Insecticide selections for PMI-supported IRS should continue to be informed by evidence/experience within each country, and if changes in insecticide class are made, the effect on mosquito densities and resistance should be monitored.

#### ***Key Issue 6: Monitoring and Evaluation of IRS***

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

***Key issue: Next-generation nets and IRS***

- There is little information on the use of next-generation 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, next-generation nets and IRS should only be considered for use in the same areas only if sufficient vector control is in place in the rest of the malarious areas in the country.

## Frequently Asked Questions for IRS

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

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

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

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

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

A. **No, not currently.** In select countries, PMI has supported IRS with DDT starting first in 2006, but the emergence of high levels of DDT resistance has limited its use, and no PMI-supported IRS program has used DDT since 2012. Furthermore, there are issues regarding the supply of quality DDT. PMI will continue to provide technical assistance on the use of DDT where there is an approved supplemental environmental assessment (SEA) in place and when appropriate given susceptibility profiles, ensuring always that appropriate safeguards are in place to prevent leakage into the agricultural sector and mechanisms for safe disposal of unused DDT and DDT-contaminated materials exist. **These additional safeguards are costly, and the supplemental environmental assessments for DDT should be initiated at least one year prior to use and require yearly revisions.** Any country using DDT for IRS should have signed and be in compliance with the Stockholm Convention for use of DDT, including the requirement of prior notification of intent to use.

Information on the Stockholm Convention can be found at:

<http://chm.pops.int/Home/tabid/2121/mctl/ViewDetails/EventModID/7595/EventID/447/xmid/7598/Default.aspx>. For more information on the use of DDT in IRS programs, refer to the WHO

position statement revised in 2011, located at:

[http://www.who.int/malaria/publications/atoz/who\\_hgm\\_gmp\\_2011/en/](http://www.who.int/malaria/publications/atoz/who_hgm_gmp_2011/en/).

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

A. It is the shared responsibility of in-country PMI team members (particularly the Activity Manager of the IRS 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 other year through the ECOS mechanism. Countries should allocate ~\$40,000 for this assessment. 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

A best management practices manual was developed in 2010 and revised in 2015 to assist PMI managers and IRS implementing partners in monitoring compliance efforts. The *PMI Best Management Practices for IRS* contains checklists for field evaluations and can be found at <http://pmi.gov/docs/default-source/default-document-library/tools-curricula/best-practices-indoor-residual-spraying-feb-2015.pdf?sfvrsn=4>. In addition, PMI through the PMI AIRS project has developed several supervisory tools and checklists which are available at <http://www.africaairs.net/wp-content/uploads/2012/08/AIRS-Supervisory-Toolkit.pdf>.

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

A. USAID has historically interpreted “the procurement or use of pesticides” clause under Reg. 216 to mean both direct and indirect forms of support (e.g., disposal of pesticides, provision of fuel to transport pesticides, technical assistance to pesticide management, etc.). This clause is of particular importance for PMI because (1) as host-country capacity grows for IRS, PMI's role will likely shrink, and (2) as more countries prioritize IRS as a key component of malaria control, funds from other donors, the private sector, and NGOs will be used for IRS, and PMI may be called upon to play a more limited role, such as provision of technical assistance and supervision, etc.

In all cases, PMI-supported countries must document the specific actions a USAID Mission/PMI program is proposing to support in the form of a new SEA or an amendment to the existing SEA.



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

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

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

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

**A. Yes.** PMI can support the direct implementation of IRS and/or provide technical assistance to other entities conducting IRS in refugee and IDP camps/settlements, as long as this is a direct request from the government and the NMCP is supportive. Note that not all refugee and IDP camp structures may be considered eligible for IRS, as non-permeable tenting material may not absorb insecticide.

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# MALARIA IN PREGNANCY

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## \*New/Key Messages\*

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

**IPTp3+ is now the primary indicator recommended by the RBM MERG.** PMI recommends tracking both IPTp3+ and IPTp2+ for MIP programming results.

In July 2017 the WHO MPAC reviewed recent studies on **MIP in low-transmission settings**. Until further data are made available, IPTp-DP is still not recommended for malaria prevention in pregnant women. In low-transmission settings where Single Screening and Treatment is routinely implemented for all women presenting at ANC, Intermittent Screening and Treatment did not result in detection of significantly more malaria infections and is still not recommended.

SP resistance monitoring should be included in all PARMA countries with no information on molecular markers of SP resistance in the previous two years. In countries where TES is performed annually in different sites, consideration should be given to annual monitoring, as resistance markers can be quite focal.

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

## Introduction

Each year, approximately 125.2 million women living in malaria-endemic countries,<sup>58</sup> including 30 million in Africa, become pregnant. For these women, malaria is a threat to both themselves and to their babies, with an estimated 10,000 maternal and up to 200,000 newborn deaths each year as a result of malaria in pregnancy. Pregnant women, particularly those in their first or second pregnancies, are particularly vulnerable to malaria as pregnancy reduces a woman's immunity to malaria, making her more susceptible to malaria infection and increasing the risk of illness, severe anemia, and death. For the unborn child, maternal malaria increases the risk of

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<sup>58</sup> Dellicour S, Tatem AJ, Guerra CA, Snow RW, ter Kuile FO (2010) Quantifying the Number of Pregnancies at Risk of Malaria in 2007: A Demographic Study. PLoS Med 7(1): e1000221. doi:10.1371/journal.pmed.1000221

miscarriage, stillbirth, premature delivery, and low birth weight - a leading cause of child mortality.<sup>59</sup>

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

In contrast, women living in areas of sub-Saharan Africa with moderate to high levels of malaria transmission may have asymptomatic infections during pregnancy, resulting in maternal anemia, which can have severe consequences for the fetus and newborn. Maternal anemia and the presence of parasites in the placenta impair fetal nutrition, contributing to a range of negative pregnancy outcomes including low-birth weight.

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

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

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

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

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<sup>59</sup> <http://www.who.int/features/2003/04b/en/>;  
[http://www.who.int/malaria/high\\_risk\\_groups/pregnancy/en/index.html](http://www.who.int/malaria/high_risk_groups/pregnancy/en/index.html)

## Intermittent Preventive Treatment in Pregnancy

IPTp is the periodic dosing of a pregnant woman with a curative treatment of an antimalarial, regardless of the presence of parasitemia, since placental infections may not be detected through standard methods. Currently, the only recommended regimen by WHO is sulfadoxine-pyrimethamine (SP), which has been shown to be safe and effective for use in pregnancy. The purpose is to clear (or substantially lower) the parasites from the placenta and to provide protection against new infections during the course of the pregnancy. This strategy has proven to be effective in preventing parasitemia and anemia in the mother, and in increasing the birth weight, and thus the chances of survival, for the newborn.<sup>60</sup>

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

In October 2012, WHO revised its policy recommendations on IPTp-SP to call for administration of **IPTp-SP at each scheduled antenatal care visit** starting as early as possible in the second trimester (13 weeks), provided that there has been an interval of approximately one month since the last dose of SP.<sup>61,62,63</sup> This change was made as a result of recent 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).<sup>64,65,66,67</sup>

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<sup>60</sup> ter Kuile, F. O., A. M. van Eijk, et al. (2007). "Effect of Sulfadoxine-Pyrimethamine Resistance on the Efficacy of Intermittent Preventive Therapy for Malaria Control During Pregnancy." *JAMA* **297**(23): 2603-2616.

<sup>61</sup> WHO Malaria Policy Advisory Committee and Secretariat (2012). "Malaria Policy Advisory Committee to the WHO: conclusions and recommendations of September 2012 meeting." *Malaria Journal* **11**(1): 424.

<sup>62</sup> [http://www.who.int/entity/malaria/iptp\\_sp\\_updated\\_policy\\_recommendation\\_en\\_102012.pdf](http://www.who.int/entity/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf)

<sup>63</sup> [http://www.who.int/malaria/mpac/sep2012/iptp\\_sp\\_erg\\_meeting\\_report\\_july2012.pdf](http://www.who.int/malaria/mpac/sep2012/iptp_sp_erg_meeting_report_july2012.pdf)

<sup>64</sup> Filler, S. J., P. Kazembe, et al. (2006). "Randomized Trial of 2-Dose versus Monthly Sulfadoxine-Pyrimethamine Intermittent Preventive Treatment for Malaria in HIV-Positive and HIV-Negative Pregnant Women in Malawi." *J Infect Dis* **194**(3): 286-293.

<sup>65</sup> Kayentao K, et al, 2013. Intermittent preventive therapy for malaria during pregnancy using 2 vs 3 or more doses of sulfadoxine-pyrimethamine and risk of low birth weight in Africa: Systematic review and meta-analysis. *JAMA* **309**: 594-604.

<sup>66</sup> Diakite, O. S. M., K. Kayentao, et al. (2011). "Superiority of 3 Over 2 Doses of Intermittent Preventive Treatment With Sulfadoxine-Pyrimethamine for the Prevention of Malaria During Pregnancy in Mali: A Randomized Controlled Trial." *Clin Infect Dis* **53**(3): 215-223.

### Current WHO IPTp Policy Recommendations

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

## 2016 WHO ANC Guidelines

The WHO ANC Guidelines, released in late 2016, call for a minimum of 8 contacts with a health provider, with one contact during the first 12 weeks gestation, and subsequent contacts at 20, 26, 30, 34, 36, 38 and 40 weeks gestation.<sup>68</sup> The ANC guidance also notes that “frequency and exact timing of some of these ANC practices and interventions – especially related to malaria, tuberculosis and HIV – may need to be adapted, based on the local context, population and health system.” As highlighted in the RBM ANC brief, developed in close collaboration with WHO Reproductive Health and Global Malaria colleagues, in malaria endemic areas, **an additional visit at 13-16 weeks is recommended to allow for early provision of IPTp.**<sup>69</sup> Ideally, this would mean that women would be given IPTp at **each** visit starting from 13-16 weeks, provided that the last dose of IPTp-SP was at least 4 weeks prior, as follows:

Timing of Contact	Dose #
1: Up to 12 weeks	ITN provided
<b>1a: 13-16 weeks</b>	<b>IPTp-SP dose 1 (additional contact)</b>
2: 20 weeks	IPTp-SP dose 2
3: 26 weeks	IPTp-SP dose 3
4: 30 weeks	IPTp-SP dose 4
5: 34 weeks	IPTp-SP dose 5
6: 36 weeks	No SP, if last dose received <1 month ago
7: 38 weeks	IPTp-SP dose 6 (if no dose in past month)
8: 40 weeks	

<sup>67</sup> Kayentao K, et al, 2013. Intermittent preventive therapy for malaria during pregnancy using 2 vs 3 or more doses of sulfadoxine-pyrimethamine and risk of low birth weight in Africa: Systematic review and meta-analysis. JAMA 309: 594-604.

<sup>68</sup> <http://apps.who.int/iris/bitstream/10665/250800/1/WHO-RHR-16.12-eng.pdf?ua=1>

<sup>69</sup> [www.rollbackmalaria.com/organizational-structure/working-groups/mipwg/](http://www.rollbackmalaria.com/organizational-structure/working-groups/mipwg/)

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, and at least 4 weeks has elapsed since the prior dose was administered. In training documents, one could consider highlighting that the visits should occur approximately monthly starting at 26 weeks, with biweekly visits starting at week 34 until the end of pregnancy.

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

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

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

In all cases where PMI is procuring SP, only those drug products that are either produced in facilities in compliance with current Good Manufacturing Practices (GMP) as evaluated using International Conference on Harmonization, WHO, or stringent regulatory authority (SRA) guidelines, *or* approved for marketing by an SRA<sup>70</sup> can be procured. In cases where countries are procuring SP themselves (i.e., not PMI procured), either from a local manufacturing facility or internationally but from a source where the quality standards and certification are unknown, teams should consider periodic testing of drug quality to ensure that high quality drugs are being used.

In the case, however, where PMI funds will be used to support the storage, distribution and/or usage of locally-sourced SP that has not been procured through PMI directly, the full

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<sup>70</sup>This could include, for example, the US FDA-approved product, Fansidar. In such cases, no quality testing is necessary as the US FDA qualifies as a stringent regulatory authority. For a complete list of SRAs, see the International Conference on Harmonization website at <http://www.ich.org/>.

consignment will be subject to 100% batch testing before release. In a drug quality survey conducted by WHO, 33 out of 127 (26%) samples of SP (from 25 batches, produced by 18 different manufacturers) were found non-compliant in tests of the content of active ingredients,<sup>71</sup> and in one study in Kenya, 45% of SP was found to be substandard.<sup>72</sup> Depending on the manufacturer, SP has a reported shelf life of between 36 and 48 months.

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

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

Although in some areas, particularly in East Africa, high levels of SP resistance have been documented, rendering SP ineffective as therapy for acute malaria infection, the available data suggest that there is still a benefit of giving IPTp-SP, and WHO continues to recommend its use, irrespective of SP resistance. Currently, there are no approved preventative treatment alternatives to IPTp-SP. WHO recommends continuing with the existing platform using SP rather than stopping and restarting with a different drug. At the present time, there is not enough evidence to recommend a wide scale policy change in favor of IPTp with dihydroartemisinin-piperaquine

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<sup>71</sup> WHO, Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. Quality Assurance and Safety: Medicines Essential Medicines and Pharmaceutical Policies. January 2011.

<sup>72</sup> Amin A, et al. The quality of sulfadoxine-pyrimethamine and amodiaquine products in the Kenyan retail sector. *J Clin Pharm Ther*, 30:6 (2005).

(DP), and WHO has recommended additional research to better understand the impact, safety, and operational feasibility associated with IPTp-DP, which would need to be delivered as a treatment course over three days rather than as a single dose at each ANC. PMI is supporting a study to further assess IPTp with DP in Malawi. In addition, a multi-country study (Tanzania, Kenya, Malawi) funded by the European and Developing Countries Clinical Trials Partnership is expected to begin in early 2018 to definitively address this question.

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

## Opportunities for Community-Based Programming

Although community-based delivery of IPTp with SP has not been approved by WHO, and WHO recommends that IPTp be delivered at routine ANC visits, WHO does support exploring partnerships to deliver some components of the proposed malaria prevention and control package to pregnant women. As such, “community health workers may be effective at promoting the use of ANC services and ITNs and, with appropriate training and logistic support, could deliver IPT.”<sup>73</sup>

Community MIP interventions appear to work best if volunteers are specifically taught to focus on both ANC and IPTp-SP. One option that has been shown to be effective in improving IPTp uptake and ANC coverage is to promote IPTp and ANC attendance at community-level to ensure that women visit the ANC to receive their IPTp doses. Few studies have assessed the effects of community level delivery of IPTp-SP. These studies have shown mixed results with regard to ANC attendance. As we do not want to promote a policy to improve IPTp at the expense of ANC attendance, additional research is needed to assess whether delivery of IPTp-SP at the community level is cost-effective and can be achieved without compromising ANC attendance. A PMI funded study in Burkina Faso of community distribution of IPTp showed a significant improvement in the delivery of IPTp3 and IPTp4, as well as improved retention in ANC. A second study in Malawi is on-going. Also, UNITAID has launched a new 4-country study to pilot community-delivery of IPTp with SP in DRC, Nigeria, Madagascar, and Mozambique. These studies will generate evidence for WHO’s policy on c-IPTp. If additional countries wish to consider this option, it would need to be assessed with an OR study before moving to wide scale

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<sup>73</sup> WHO Regional Office for Africa: A Strategic Framework for Malaria Prevention and Control During Pregnancy in the African Region (2004).



implementation. Countries interested in exploring community-based distribution of IPTp-SP should discuss this with the PMI Headquarters MIP Team. An alternate implementation approach to increase uptake of IPTp for countries to consider would be to expand their facility-based ANC outreach services to include IPTp (along with delivery and promotion of the full ANC package) as a means of reaching pregnant women in remote, rural areas.

## Insecticide-Treated Mosquito Nets

Use of ITNs during pregnancy is a key component of PMI's malaria in pregnancy strategy. In areas with moderate to high levels of transmission, the use of ITNs during pregnancy provides significant protection against malarial infection, illness, maternal anemia, and low birth weight.<sup>74</sup> The provision of ITNs to pregnant women is part of the essential package of ANC services. ITNs should be provided to pregnant women as early as possible in pregnancy and their use should be encouraged for women throughout pregnancy and during the postpartum period. ITNs and IRS are the only interventions that protect women early in pregnancy, during the first trimester. Ideally, **all women of childbearing age should sleep under an ITN**, as this will ensure protection even before the woman realizes that she is pregnant. PMI supports universal coverage of ITNs to ensure women of reproductive age sleep under ITNs early in their pregnancy; PMI teams are encouraged to identify additional novel distribution channels to ensure high coverage of nets to women of reproductive age, particularly adolescent girls. **With continuing support for universal ITN coverage campaigns and maintaining high ITN ownership, countries should not lose sight of the importance of providing ITNs to pregnant women at first ANC visit as part of the routine health services.** Although mass campaigns are critical to ensure universal coverage is achieved, when planning a campaign, ensure that sufficient ITNs are available so that ITNs are not removed from the ANC clinics resulting in a prolonged period of unavailability following the campaign. The RBM Malaria in Pregnancy and Vector Control Working Groups and the Alliance for Malaria Prevention published a joint statement detailing the importance of maintaining LLIN coverage of vulnerable populations via ANC and EPI distribution.<sup>75</sup>

## 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

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<sup>74</sup> Gamble, C., Ekwaru JP, ter Kuile FO (2006). "Gamble C, Ekwaru JP, ter Kuile FO. Insecticide-treated nets for preventing malaria in pregnancy." *Cochrane Database of Systematic Reviews* **CD003755**.

<sup>75</sup> [http://www.rollbackmalaria.org/files/files/partnership/4\\_FLLIN\\_E.PDF](http://www.rollbackmalaria.org/files/files/partnership/4_FLLIN_E.PDF)

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

For uncomplicated malaria, WHO continues to recommend that women in the first trimester should be treated with oral quinine for seven days (with or without clindamycin), however, the Technical Expert Group on Malaria Chemotherapy is expected to review the safety data and make a recommendation on whether ACTs can be considered equivalent to quinine for treatment of acute malaria in the 1<sup>st</sup> trimester of pregnancy in early 2018. Until the recommendation is changed, however, ACTs should be used for treating uncomplicated first trimester malaria infections only if no other efficacious antimalarial treatments are available. In the second and third trimesters, ACTs are the preferred therapy. Quinine is associated with an increased risk of hypoglycemia in late pregnancy, and it should be used only if efficacious alternatives are not available. Primaquine and tetracycline should not be used in pregnancy.

For treatment of severe malaria in pregnancy, parenteral antimalarials should be given without delay; maternal mortality in severe malaria is approximately 50%, which is higher than in non-pregnant adults. Parenteral artesunate is preferred in the second and third trimesters while either parenteral quinine or parenteral artesunate are acceptable choices in the first trimester (the increased risk of death outweighs the uncertainties over safety).<sup>76</sup>

<b>Table 2. Treatment of Malaria in Pregnancy</b>		
	<b>1<sup>st</sup> trimester</b>	<b>2<sup>nd</sup> or 3<sup>rd</sup> trimester</b>
<b>Uncomplicated malaria</b>	Oral quinine for seven days (with or without clindamycin)	ACT*
<b>Severe malaria</b>	IV/IM artesunate or IV/IM quinine	IV/IM artesunate (preferred) or IV/IM quinine if artesunate not available

<sup>76</sup> WHO, 2012. Management of severe malaria: a practical handbook – 3rd ed.

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

## HIV-Infected Women

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

**Intermittent preventive treatment is recommended for HIV-infected pregnant women living in areas with high levels of transmission only when they are not receiving daily trimethoprim-sulfamethoxazole (cotrimoxazole) prophylaxis, because co-administration of these drugs increases the risk of sulfa-related adverse effects, including Stevens-Johnson Syndrome (a severe skin reaction).** In addition, daily cotrimoxazole provides a similar protective effect to IPTp if doses are not missed.<sup>77</sup> HIV-infected women who are not taking cotrimoxazole prophylaxis should receive a minimum of three doses of IPTp with SP during pregnancy, in order to obtain protection similar to that received with two doses in women not infected with HIV.

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

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

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<sup>77</sup> Kapito-Tembo et al., Marked reduction in prevalence of malaria parasitemia and anemia in HIV-infected pregnant women taking cotrimoxazole with or without sulfadoxine-pyrimethamine intermittent preventive therapy during pregnancy in Malawi. *J Infect Dis.* 2011 Feb 15;203(4):464-72.

adequate to prevent neural tube defects in the infant.<sup>78</sup> 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.<sup>79</sup> In contrast, the 0.4 mg/day dose does not interfere with SP efficacy. **In countries where doses of folic acid greater than 1 mg/day are used for supplementation in pregnancy (notably Angola, Niger and Nigeria), PMI teams should work with the MOH to procure (or consider procuring) low-dose folic acid (or iron and folate combination tablets, with 60 mg/day iron and 0.4 mg/day of folate), which is recommended by WHO for use in pregnancy.**

## Improving Program Implementation for IPTp

A number of challenges to IPTp scale up have been observed in PMI-supported countries. These include issues concerning central and peripheral level stock-outs of SP, inconsistent malaria and maternal health guidance on IPTp administration, confusion among providers about timing and dosages, and lack of coordination between Reproductive/Maternal Health and NMCPs of their responsibilities for program implementation (please see **Table 3** for a list of remaining barriers by health system component and possible solutions).

PMI country teams are encouraged to:

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

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<sup>78</sup> [http://www.who.int/maternal\\_child\\_adolescent/documents/924159084x/en/index.html](http://www.who.int/maternal_child_adolescent/documents/924159084x/en/index.html)

<sup>79</sup> Ouma P, et al. (2006) A randomized controlled trial of folate supplementation when treating malaria in pregnancy with sulfadoxine-pyrimethamine. PLoS Clin Trials 1(6): e28.

- Consider support for electronic based supervision and reporting forms to assess health worker performance
- Work toward ensuring proper folic acid doses are being administered

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

## Additional Resources

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

## Frequently Asked Questions for MIP

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

A. The spread of resistance of *P. falciparum* to SP in eastern and southern Africa has raised concerns about the efficacy of SP for IPTp. However, even in areas where SP is not an effective therapy in children for treating uncomplicated malaria, it remains effective for IPTp. It is thought that pregnant woman's pre-existing immunity amplifies the effectiveness of SP in IPTp, whereas young children have no such immunity.<sup>80</sup> 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. There is evidence of decreasing efficacy of SP in Eastern Africa, specifically in studies from Tanzania and Malawi, suggesting that SP maybe of reduced benefit in specific regions of the respective countries.<sup>81,82,83</sup> Of particular concern are several studies in areas where the dihydropteroate synthase (*dhps*) A581G mutation has been identified on a background of the dihydrofolate reductase (*dhfr*) /*dhps* quintuple mutant, resulting in a "sextuple mutant."<sup>84</sup> 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.<sup>85</sup> In a study in Mozambique, Menendez et al. found a protective effect of SP against neonatal death despite a lack of protection from low birth weight or placental infection by histology, suggesting that there may be additional mechanisms through which SP provides protection.<sup>86,87</sup> Studies in areas with

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<sup>80</sup> ter Kuile FO, et al: Effect of Sulfadoxine-Pyrimethamine Resistance on the Efficacy of Intermittent Preventive Therapy for Malaria Control During Pregnancy. *JAMA* 2007, 297:2603-2616.

<sup>81</sup> Harrington WE, et al: Intermittent Treatment to Prevent Pregnancy Malaria Does Not Confer Benefit in an Area of Widespread Drug Resistance. *Clin Infect Dis* 2011, 53:224-230.

<sup>82</sup> Feng G, et al: Decreasing burden of malaria in pregnancy in Malawian women and its relationship to use of intermittent preventive therapy or bed nets. *PLoS ONE* 2010, 5:e12012.

<sup>83</sup> Harrington WE, et al: Competitive facilitation of drug-resistant *Plasmodium falciparum* malaria parasites in pregnant women who receive preventive treatment. *Proc Natl Acad Sci U S A* 2009, 106:9027-9032.

<sup>84</sup> Minja D, et al., 2013. Infections with *Plasmodium falciparum* sextuple dihydrofolate reductase/dihydropteroate synthetase allelic haplotypes during pregnancy are associated with decreased birth weight in Korogwe, Tanzania. *Emerg Inf Dis*. 19.

<sup>85</sup> Kayentao K, et al, 2013. Intermittent preventive therapy for malaria during pregnancy using 2 vs 3 or more doses of sulfadoxine-pyrimethamine and risk of low birth weight in africa: Systematic review and meta-analysis. *JAMA* 309: 594-604.

<sup>86</sup> Menendez, C., A. Bardaji, et al. (2010). "Malaria Prevention with IPTp during Pregnancy Reduces Neonatal Mortality." *PLoS ONE* 5(2): e9438.

lower levels of SP resistance (West Africa) have found that IPTp with SP remains effective.<sup>88,89</sup> In addition, a recent meta-analysis of national survey data has shown that SP provides protection in a programmatic context (e.g., non-study setting).<sup>90</sup> 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.<sup>91</sup> Consequently, WHO recommends continuing IPTp with SP until such time as there is clear evidence that it is no longer effective or an effective alternative is recommended. The updated WHO policy recommendations are based on the recent evidence and seek to reinforce the importance and appropriateness of SP for IPTp. PMI also encourages routine monitoring of molecular markers of SP resistance.

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

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

- Counting weeks from the first day of the last menstrual period
- Palpation of the uterine fundus: once the fundus can be palpated, the woman is definitely in the 2<sup>nd</sup> trimester, although an unskilled provider may not be able to palpate the fundus as early as 13 weeks
- Quickening, which is defined as when the mother first feels fetal movements, and usually occurs at approximately 20 weeks gestation in the first pregnancy, and earlier (between 15-20 weeks) in subsequent pregnancies (given that this is well into the 2<sup>nd</sup> trimester, it is preferred that other methods be used to determine gestational age/ whether the woman is in the 2<sup>nd</sup> trimester)

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<sup>87</sup> Menéndez, C., A. Bardají, et al. (2008). "A Randomized Placebo-Controlled Trial of Intermittent Preventive Treatment in Pregnant Women in the Context of Insecticide Treated Nets Delivered through the Antenatal Clinic." *PLoS ONE* 3(4): e1934.

<sup>88</sup> Maiga OM, et al: Superiority of 3 Over 2 Doses of Intermittent Preventive Treatment With Sulfadoxine-Pyrimethamine for the Prevention of Malaria During Pregnancy in Mali: A Randomized Controlled Trial. *Clin Infect Dis* 2011, 53:215-223

<sup>89</sup> Likwela JL, et al. Sulfadoxine-pyrimethamine resistance and intermittent preventive treatment during pregnancy: a retrospective analysis of birth weight data in the Democratic Republic of Congo (DRC). *Trop Med Int Health*. 2011

<sup>90</sup> Eisele, TP, Larsen DA, et al. (2012). Malaria prevention in pregnancy, birthweight, and neonatal mortality: a meta-analysis of 32 national cross-sectional datasets in Africa. *Lancet Inf Dis* 12:(12):942-949.

<sup>91</sup> Desai M, Gutman J, et al. Impact of Sulfadoxine-Pyrimethamine Resistance on Effectiveness of Intermittent Preventive Therapy for Malaria in Pregnancy at Clearing Infections and Preventing Low Birth Weight. *Clin Infect Dis*. 2015 Oct 20. pii: civ881.

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# SEASONAL MALARIA CHEMOPREVENTION

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

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

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

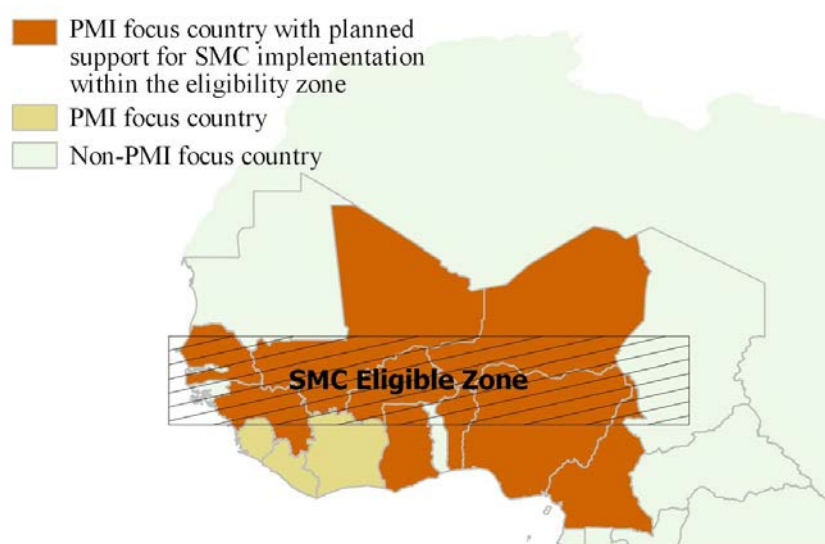
## **Introduction**

WHO issued a recommendation for the implementation of seasonal malaria chemoprevention (SMC) in March, 2012. Seasonal malaria chemoprevention, formerly known as intermittent preventive treatment for children, is the administration of treatment doses of longer-acting antimalarial medications at monthly intervals in areas of exclusively seasonal transmission with the aim of treating any existing infections and maintaining protective drug concentrations in the blood throughout a complete transmission season. The current WHO recommendations consist of a treatment dose of amodiaquine plus sulfadoxine-pyrimethamine (AQ+SP) given to children between 3 and 59 months of age at monthly intervals during the malaria transmission season, up to a maximum of four doses.

This approach is only recommended for geographic regions where the duration of the malaria transmission season is four months or less. Seasonal malaria chemoprevention is not recommended for areas where high-levels of resistance to either SP or AQ have been demonstrated. Based on these criteria, implementation of this strategy is only recommended in countries or portions of countries in the Sahel region of West Africa. WHO recommends that countries implementing SMC should not concurrently implement intermittent preventive treatment in infants (IPTi, which is the administration of a full treatment dose of SP to infants less than one year of age) in the same areas. PMI currently supports SMC activities in Benin, Burkina Faso, Cameroon, Ghana, Guinea, Mali, Niger, Nigeria and Senegal. Seasonal malaria chemoprevention is not recommended 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 and efficacy of alternative drugs for SMC programs are lacking.



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



## Considerations

A number of technical and logistical considerations exist when supporting an SMC program.

### *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. However, WHO has not yet conducted an evidence review or made a recommendation regarding this age group. For this reason, PMI-funded programs should adhere to the current WHO age definitions.

## *Time frame*

Seasonal malaria chemoprevention should be delivered once a month during the peak transmission season, not to exceed four months of implementation in a given year. Some countries have questioned whether three rounds would be sufficient to provide a desired level of protection, while others have considered extending the season to five months or more. Currently, WHO does not recommend extending the SMC season beyond four months to prevent accelerated development of resistance to the drugs. 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.

## *Implementation issues*

The current WHO guidance does not provide details on the best strategies for delivery of SMC in the field. In many countries, the first dose SMC is delivered door-to-door by community health workers, and the doses for the second and third day are left with the child's caregiver, along with instructions for administration. In other countries, a fixed-point approach is used for the first dose, with caregivers taking the additional doses for home administration. In fixed-point sites, there may also be community level 'mop-up' to reach children not seen at the distribution points. Some programs couple other interventions, such as nutritional supplementation, to SMC delivery. In most programs, SMC is given to all children who present, but there are exceptions. For example, in Mali, malaria screening and testing is done prior to SMC delivery and children who test positive are treated with ACTs and do not receive SMC drugs. Countries have adopted different delivery approaches that are adapted to the specific country context. While no official guidance exists, the individual experiences of different countries have been documented in the scientific literature. For example, a PEER study funded by PMI documented that door-to-door distribution achieved higher coverage levels, but also increased costs for the program. PMI countries teams are encouraged to reach out to the Resident Advisors, and NMCP staff, in other countries implementing SMC to better understand best practices.

## *Resistance monitoring vs. pharmacovigilance*

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

for treatment of clinical malaria in a standard TES protocol. PMI is working with WHO and other partners to develop and implement molecular methods to monitor for resistance to these two drugs. Country teams interested in supporting resistance monitoring activities should consult with the Case Management team for guidance.

## *Commodities*

One significant issue for implementing an SMC program is having the necessary quantities of quality-assured SP+AQ available in advance of the malaria transmission season. In the past, individual tablets for SP and AQ were purchased separately, necessitating relatively complicated cutting to prepare the appropriate age-based combination treatment dosages, especially for children under one year of age who require smaller doses. In 2014, one manufacturer received approval from the WHO Prequalification Program for non-dispersible formulated co-blister presentation of SP+AQ. Additionally, there is a dossier for a dispersible co-blister formulation of SP+AQ currently under review by the WHO PQ Program; PMI can procure both the dispersible and non-dispersible co-blisters, and these products are preferable over the loose pills used in the past. Regardless of formulation, lead times are long (approximately 1 year) and countries considering drug procurement in support of SMC campaigns should place orders as early as possible to ensure the drugs arrive in country in time for the malaria transmission season, taking into consideration customs clearance, the possible need for drug registration waivers, and 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. See the **Commodity Procurement** and **Supply Chain Management** chapters for additional information.

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

It is recommended that countries do specific quantification for RDT and ACT needs during the SMC distribution rounds as part of the logistics planning, as the additional testing of febrile children during these rounds (in countries where active screening and treating is part of the SMC protocol) might result in a seasonal increase in the needs for ACTs and RDTs.

## *Surveillance, monitoring, and evaluation*

As a geographically targeted program, SMC presents some unique challenges for surveillance, monitoring, and evaluation. The first challenge is enumerating the target population of children 3-59 months. While most districts (or health zones, etc.) have estimates for this figure, precision is often difficult; some children will age into, and out of, this range during the period of

implementation and older siblings or children from outside the SMC geographic area may present for treatment. Enumeration of the eligible population has implications for planning and procurement of drugs as well as for estimates of SMC coverage.

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

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

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

This indicator is intended to be derived from routine systems such as those mentioned above. Despite this being the official WHO-recommended indicator, the measurement details have not been fully finalized. Ideally, coverage would mean each child has received all three daily doses of medication each month, over the three or four months of the transmission season. In reality, the routine data generally just reflect the children who received the first dose through directly-observed treatment and whose caregivers were given the remaining two doses to administer at home. Most routine information systems are not able to capture actual administration of the second and third dose. However, PMI's pilot studies indicated that if a child received the first directly observed therapy dose, there was a very high likelihood of receiving the additional doses at home<sup>92</sup>. The number of rounds (months) of administration can vary by country and even by sub-national zone depending on a range of planning factors. Thus, countries should also report on the target number of courses (3 or 4) and calculate this indicator accordingly.

In addition, it will be important to monitor the proportion of children who meet the eligibility criteria (including residence in eligible zones) but who did not receive SMC due to refusals, presenting with malaria (in the case of Mali), etc. During the pilot phases of SMC scale-up, a number of programs used pre- and post-coverage surveys to capture direct data on coverage of the intervention. However, now that SMC has moved beyond the pilot phase, such surveys can be prohibitively expensive and can increase the overall costs of the intervention. For this reason, PMI does not recommend using coverage surveys as a means to monitor the intervention.

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<sup>92</sup> Diawara F et. al. Measuring the impact of seasonal malaria chemoprevention as part of routine malaria control in Kita, Mali [Malar J.](#) 2017 Aug 10;16(1):325.

Similarly, PMI does not recommend tracking coverage of SMC through national household surveys such as the DHS or MIS. Instead, PMI will work with NMCPs to report SMC implementation results using program data. The reason is that 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 (similar issues arise with IRS programs). 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 RBM Monitoring and Evaluation Reference Group (MERG) has convened an SMC Task Force to review these tools and make recommendations on a consistent approach to program monitoring.

Additional information on the WHO policy recommendation can be found at:  
[http://www.who.int/malaria/publications/atoz/smc\\_policy\\_recommendation\\_en\\_032012.pdf](http://www.who.int/malaria/publications/atoz/smc_policy_recommendation_en_032012.pdf)

A field guide for SMC implementation from WHO is available here:  
<http://www.who.int/malaria/publications/atoz/9789241504737/en/>

An additional toolkit from MMV is available at:  
<https://www.mmv.org/access/tool-kits/seasonal-malaria-chemoprevention-tool-kit>

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# VACCINES AND OTHER PREVENTIVE APPROACHES

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

WHO is conducting a **pilot evaluation of RTS,S implementation** in three countries to assess feasibility, safety, and impact (mortality) in programmatic conditions. The vaccine implementation evaluation began in Ghana in April 2019 and will likely start in Kenya and Malawi later this year.

Guidance from the 2018 WHO Evidence Review Group on **mass drug administration (MDA)** and an updated Cochrane Review including recent MDA trials will be forthcoming.

**Proactive community case management (ProCCM)** is a community-based intervention in which community health workers actively seek out persons with fever, test them, and treat those that test positive for malaria. ProCCM is being scaled up in Senegal and Madagascar after operational research demonstrated effectiveness in decreasing malaria parasite prevalence and incidence. Non-PMI supported research is ongoing in Uganda and Mali. PMI is currently planning operational research to assess whether ProCCM can have an impact on reducing malaria transmission. Other OR proposals could be considered on a case-by-case basis.

## **Introduction**

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

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

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

## Intermittent Preventive Treatment in Infants (IPTi)

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

In reality, most countries lack information on the prevalence of this mutation at the population level, making this strategy difficult to implement. To date, NMCPs have not prioritized IPTi in any country except Sierra Leone. Sierra Leone, after piloting IPTi in four districts in 2017, scaled up IPTi nationally to all 14 districts in mid-2018. WHO recommends that countries implementing SMC should not also implement IPTi in the same areas. Any requests from NMCPs to support IPTi must be discussed with the PMI Headquarters Case Management Team and PMI leadership.

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

## Malaria Vaccine

Research and development to produce a malaria vaccine has been ongoing for decades. The RTS,S/AS01 malaria vaccine was tested in 11 sites in seven African countries with different transmission intensities. The vaccine was tested in two age-categories: children first vaccinated at 5-17 months of age, and young infants first vaccinated at 6-12 weeks of age. After approximately four years of follow-up, vaccine efficacy against clinical malaria in children was 36% and 28%, and against severe malaria was 32% and 1.1% when administered with and

without a booster dose, respectively. In young infants, the vaccine efficacy against clinical malaria was lower at 26% with the booster dose and 18% without; no efficacy against severe malaria was shown. Despite moderate to low efficacy, impact, measured as number of cases averted, was high; 1,774 cases of clinical malaria were averted per 1,000 children vaccinated with booster, and 1,363 without. In young infants, 983 and 558 cases of clinical malaria were averted per 1,000 vaccinated with and without the booster, respectively. Two important safety signals were noted; an increase in meningitis and febrile seizures in RTS,S/AS01 vaccinated children compared with controls.

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

## **Mass Drug Administration**

Mass Drug Administration is defined as the practice of treating a targeted population in a defined geographic area for malaria, irrespective of the presence of symptoms and without diagnostic testing. As malaria control programs aspire to elimination, there has been a resurgent interest in MDA as a tool to eliminate the remaining parasite reservoir in a given geographic area. Mass drug administration was a strategy used with mixed results during the eradication era of the mid-20<sup>th</sup> century. In some regions, such as the USSR and China, it was used for malaria control, parasite elimination, and epidemic response. In combination with vector control measures, MDA helped to eliminate malaria in select settings (e.g., small islands or highland settings).

Based on those eradication era experiences, WHO had discouraged MDA for routine malaria control because of its limited sustained impact on transmission and the high potential for the



development of drug resistance. However, when artemisinin resistance was first detected in Southeast Asia, MDA was revived as a potential approach to eliminate the resistant strains of the parasite in limited geographic settings and targeted populations. In 2010, WHO convened an expert group to review the evidence for the use of MDA in the artemisinin-resistance containment project in Southeast Asia. The WHO Technical Experts Group concluded that there was no evidence of long-term benefits for MDA in large population groups. Two reviews found that while MDA can be successful at rapidly reducing parasite prevalence, once the activity is stopped, there is a strong tendency for malaria to rebound to previous transmission levels especially in higher transmission settings<sup>93,94</sup>. A consensus modelling study<sup>95</sup> noted that despite differing magnitude of effect depending on the transmission model used, all models predicted the percentage reduction in transmission to be temporary. The underlying assumption and the rationale for MDA is that subpatent parasitemia contributes substantially to malaria transmission and, therefore, must be treated if malaria is to be eliminated.

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

In addition, in the context of the 2014 Ebola outbreak in West Africa, MDA was used as a strategy to reduce the prevalence of malaria in selected urban areas.<sup>96</sup> Temporarily reducing the burden of malaria on the health facilities allowed health workers to focus efforts on establishing critical Ebola diagnostic and treatment protocols.

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

Preliminary results of these studies have been mixed, both in terms of the coverage achieved (which often was well below the target) and in overall effectiveness. Some of the variation in study results appears to be related to transmission level and the coverage achieved and ongoing importation of malaria infections from outside the targeted area. In addition, initial results from

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<sup>93</sup> Newby, G. et al., (2015). Review of mass drug administration for malaria and its operational challenges. *Am J Trop Med Hyg.*

<sup>94</sup> <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008846.pub2/full>

<sup>95</sup> Brady, O. J., et al. (2017). Role of mass drug administration in elimination of *Plasmodium falciparum* malaria: a consensus modelling study. *Lancet Glob Health* 5(7): e680-e687

<sup>96</sup> Aregawi, M., et al. (2016). Impact of the Mass Drug Administration for malaria in response to the Ebola outbreak in Sierra Leone. *Malar J* 15: 480.

southern Zambia showed marked reductions in malaria prevalence and incidence across both control and MDA arms following aggressive efforts to achieve universal coverage of LLINs, IRS, and effective community case management.<sup>97</sup> In addition, focal MDA (MDA targeting households or small-scale foci) was not as effective or cost-saving compared to MDA.

In 2015, WHO convened an Evidence Review Group to review all available evidence on MDA and presented their draft recommendations to the Malaria Policy Advisory Committee. In November 2015, WHO issued its recommendations stating that: *“Use of MDA for the elimination of P. falciparum malaria can be considered in areas approaching interruption of transmission where there is good access to treatment, effective implementation of vector control and surveillance, and a minimal risk of re-introduction of infection.”* The goal in this setting is to eliminate all remaining parasite carriers and fully interrupt transmission. WHO also recommends that MDA could be considered in the context of epidemics or complex emergencies to transiently reduce malaria prevalence and reduce the risk of severe disease and death, thereby reducing the burden on the health system. WHO developed a manual for organizing an MDA campaign including examples of tools, templates for developing job aids, training and communication materials, and data collection forms that may be useful.

In 2018, WHO convened another Evidence Review Group to review the role of MDA and updated guidance should be forthcoming. In addition, an update of the previous Cochrane review which includes more recent high-quality studies should be available shortly.

PMI is not currently supporting MDA implementation in the context of elimination activities or routine program support. At this point in time, PMI support for MDA is in the context of operational research. PMI will be supporting operational research to compare targeted MDA versus reactive case detection in response to index cases in the elimination settings of Ethiopia and a MDA study with or without ivermectin in Senegal. Any country teams considering supporting an MDA intervention should consult with the PMI Headquarters Elimination Working Group and Case Management Teams.

## Mass Screen and Treat

Mass screen and treat (MSaT) refers to screening all persons in a population with a malaria diagnostic test and providing treatment to those with a positive test result. The aim of this type of program is to reduce the parasite reservoir (and ultimately reduce gametocytemia) and decrease malaria transmission. By systematically testing a population and treating all positive cases,

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<sup>97</sup> Eisele, T.P. et al. (2016). Short-term Impact of Mass Drug Administration with Dihydroartemisinin Plus Piperaquine on Malaria in Southern Province Zambia: A Cluster-Randomized Controlled Trial. *J Infect Dis.*;214(12):1831-1839.

including asymptomatic infections, the hope is that the reservoir of parasites (and subsequent gametocytes) will be diminished beyond that which is possible by traditional case management.

At present, malaria RDTs are the only feasible option for conducting MSaT. However, the currently available RDTs are not sensitive enough to detect very low density parasitemias, which can comprise up to 50% of malaria infections found in a population. Evidence from Burkina Faso and Zambia, and from a PMI-supported study in Kenya, indicate that MSaT with conventional RDTs is insufficient to significantly reduce the human infection reservoir. While work to develop more field-friendly molecular tests are underway and a highly-sensitive hrp2-based RDT is commercially available, there is currently no evidence to indicate that such more sensitive diagnostic tests will improve the effectiveness of the MSaT approach. Evaluation of the performance of the high-sensitivity RDT for *P. falciparum* malaria in asymptomatic individuals from Uganda, Myanmar, and naïve human challenge infections showed a greater than 10-fold lower limit of HRP2 compared with conventional RDT.<sup>98</sup> Recent studies from Myanmar<sup>99</sup> and Ethiopia<sup>100</sup> observed higher sensitivities than the conventional RDTs but still only about 50% compared to the gold standard methods.

The 2015 Malaria Policy Advisory Group concluded that mass screening and treatment and focal screening and treatment for malaria are not recommended as interventions to interrupt malaria transmission. PMI is not currently supporting MSaT activities; however, the role of highly-sensitive RDTs in reactive case detection is being evaluated in Burma and Cambodia. Any country teams considering supporting an intervention involving MSaT should consult with the PMI Headquarters Elimination Working Group and Case Management Teams in advance of any consideration of MOP support.

## Pro-active Community Case Management

Proactive community case management (ProCCM) is deployed to identify persons of all ages with fever or other symptoms consistent with malaria on a routine basis (generally weekly) in a targeted community. With this approach, persons with fever are actively identified in the community, often by door-to-door sweeps through the catchment area, and 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 community sweeps are often restricted to the high transmission season.

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<sup>98</sup> Das, S., et al. (2017). Performance of a High-Sensitivity Rapid Diagnostic Test for Plasmodium falciparum Malaria in Asymptomatic Individuals from Uganda and Myanmar and Naïve Human Challenge Infections. [Am J Trop Med Hyg](#)

<sup>99</sup> Landier, J., et.al. (2018). Operational Performance of a Plasmodium falciparum Ultrasensitive Rapid Diagnostic Test for Detection of Asymptomatic Infections in Eastern Myanmar. [J Clin Microbiol.](#)

<sup>100</sup> Girma, S., et. al. (2018). Prevalence and epidemiological characteristics of asymptomatic **malaria** based on ultrasensitive diagnostics: A cross-sectional study. *Clin Infect Dis.*

The most well-established example of this approach is the PECADOM Plus program in Senegal. Community health workers conduct weekly visits to all households in their catchment areas during high transmission season for malaria. They interview residents to identify anyone with recent fever or symptoms related to malaria. Those reporting such symptoms are tested with an RDT. Treatment is provided to those who test positive. In villages where PECADOM Plus has been implemented, there have been significant reductions in weekly prevalence of symptomatic, parasitologically confirmed malaria infection over the course of the transmission season, even while total numbers of cases identified and treated at the community level increased.<sup>101</sup> The approach, started in the highest transmission districts, was scaled to 40 of Senegal's 76 health districts in 2016, including some zones of low transmission. Current efforts extend the period of implementation and increase the proportion of communities benefiting from this intervention.

PMI is exploring whether the ProCCM approach might be feasible and effective, both as a means of reducing severe disease and death and as a transmission reduction strategy, in other settings. Studies of ProCCM are underway, some with PMI funding, in multiple countries, including Mali, Madagascar, and Uganda. Results from Madagascar suggest that ProCCM was associated with decreased parasite prevalence among all ages and decreased anemia among women of reproductive age. More evidence is likely to become available in the next few years. The ProCCM approach may be most appropriately deployed in areas where core vector control and passive case management interventions have been fully scaled up, where an existing iCCM program is in place, and where further reduction in burden is sought. **Evidence as to feasibility/effectiveness in other settings is currently unavailable and thus PMI does not recommend ProCCM to be deployed outside of OR at this time.**

Any country considering deploying ProCCM should consult with the PMI Headquarters Case Management Team. For countries where studies have not yet been conducted, such pilots should be considered OR and have clear study questions related to effectiveness and/or feasibility.

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<sup>101</sup> Linn A, et al. Reduction in symptomatic malaria prevalence through proactive community treatment in rural Senegal. *Trop Med International Health* 2015.

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# CASE MANAGEMENT

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

**Infections with parasites containing deletions in the *hrp2* gene, which produces the main antigen detected by *P. falciparum* RDTs, have been identified in a few sites in Africa.** There is now an option to screen samples collected during therapeutic efficacy studies for the presence of the *hrp2* deletions.

**Multi-species RDTs will only be procured in countries with co-endemic *P. vivax*** (Ethiopia, Madagascar, and Greater Mekong Subregion). PMI does not procure two line multi-antigen RDTs for *P. falciparum* or highly sensitive RDTs for case management.

**Two WHO pre-qualified rectal artesunate products are now available for pre-referral treatment of severe malaria.** These 100-mg products are recommended over the previous 50-mg and 200-mg formulations, with the justification that “as 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.”

- **Artesunate-pyronaridine (ASPy or Pyramax®)** is a WHO-prequalified ACT that is registered in a number of countries but not yet part of the WHO Standard Treatment Guidelines. PMI can support TES of ASPyr in countries where it is in or being considered for the national guidelines.
- In 2018, the US FDA approved a new antimalarial, **tafenoquine**, for the radical cure and prophylaxis of *P. vivax*. Prior to administering this medication, a quantitative G6PD test must be performed. Studies are underway to better define which age groups can safely receive this medication.
- PMI does not currently recommend or advocate for the use of multiple first-line therapies (MFTs) or pre-emptive rotation of antimalarials in Africa for the purpose of delaying the emergence of drug resistance. Rotation is used in the Mekong to address proven, existing and/or evolving ACT resistance through periodic switching of first-line therapies.

## **Introduction**

A comprehensive program for malaria case management should support interventions to strengthen quality of and expand access to:

- Diagnostic testing for malaria, including both quality-assured and quality-controlled microscopy and RDTs
- Prompt and effective case management of fever in health facilities, including adherence to diagnostic test results and management of uncomplicated malaria and severe disease (including in pregnant women)
- Prompt and effective case management of fever in the community, including iCCM of pneumonia, diarrhea, and malaria in children
- Introduction and scaling-up of fever case management, including malaria diagnostic testing, in the private sector, where appropriate
- Practices for accurately recording and reporting malaria test and treatment results
- Monitoring the therapeutic efficacy of first-line antimalarial treatments
- Systems for forecasting, procuring, storing, distributing, and monitoring the quality of essential drugs and diagnostics

## Diagnostic Testing

**In 2010, WHO changed its recommendations on malaria diagnosis, calling for all patients with suspected malaria to undergo quality-assured diagnostic testing, with either microscopy or RDTs, and for treatment decisions to be based on test results.** Diagnosis based on clinical signs and symptoms alone should only be used when diagnostic testing is unavailable.

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 and quantifying malaria parasites because the blood is more concentrated allowing for a greater volume of blood to be examined. Thin smears are particularly helpful for malaria speciation. However, speciation can also be done with thick smears, and in cases where only materials for thick smears are available, microscopists may be more comfortable using this modality for all applications (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.

Malaria RDTs detect parasite antigens, specifically histidine-rich protein 2 (HRP-2), *Plasmodium* lactate dehydrogenase (pLDH), or aldolase. RDTs may remain positive for two weeks or more after clearance of parasitemia (particularly those RDTs based on the HRP-2 antigen) and are not designed for determining the density of parasitemia, which is used for monitoring response to treatment for severe malaria. Also, RDTs are less sensitive for non-falciparum malaria species.

Consistent with WHO recommendations, PMI has prioritized scaling up diagnostic testing for malaria with both microscopy and RDTs in all focus countries with the goals that all persons

with suspected malaria are tested and only those with a positive test are treated for malaria. This requires that quality-assured diagnostic testing for malaria be available at all levels of the health care system, including at the community level, at all times. In most countries, microscopy is only available at the hospital level and at larger health centers. In contrast, RDTs are being used at all levels. Each country must decide which of these two tests should be used at which points-of-care and for what indications. Microscopy, though, should be available in settings where severe malaria patients are treated (i.e., referral facilities). In contrast, RDTs are the best option in settings where a laboratory is not available (e.g., at lower level health facilities and the community level).

## Case Management

### *Treatment of uncomplicated malaria*

PMI supports the WHO guidance recommending that patients with parasitologically confirmed malaria (or suspected malaria, if diagnostic testing is not available) be categorized as having either uncomplicated or severe disease for the purposes of prescribing treatment. Uncomplicated malaria is defined as symptomatic malaria without signs or symptoms of severity or evidence of vital organ dysfunction (see severe malaria below).

For uncomplicated malaria, WHO recommends ACTs as the first-line treatment.<sup>102</sup> ACTs partner an artemisinin drug (e.g., artesunate, artemether, dihydroartemisinin) with a second antimalarial that has a longer half-life. Artemisinins rapidly reduce parasite density in the blood and control fever. Side effects are uncommon, and serious or life-threatening adverse drug reactions are exceedingly rare. When combined with a second antimalarial, such as mefloquine, SP, amodiaquine, lumefantrine, or piperaquine, a 3-day course is usually curative. Monotherapy with artemisinin compounds is not recommended by WHO or PMI, except for initial or pre-referral treatments of severe malaria with non-oral (i.e., intravenous or intramuscular, or rectal if pre-referral) artesunate, which is followed by a full course of ACT.

Five ACTs are recommended by WHO as first-line treatment of uncomplicated malaria:

1. Artemether-lumefantrine
2. Artesunate-amodiaquine
3. SP-artesunate
4. Mefloquine-artesunate
5. Dihydroartemisinin-piperaquine

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<sup>102</sup> [WHO Guidelines for the treatment of malaria, 3<sup>rd</sup> edition, 2015](#)

The determination of the recommended first-line ACT should be based on the known therapeutic efficacy in the respective country. In areas where either amodiaquine or SP has been used for SMC or extensively as monotherapy leading to the development of resistance to these drugs, combinations of either drug with artesunate may not be ideal choices for first-line treatment. Mefloquine-artesunate is recommended only for areas of multi-drug resistance (i.e., parts of Southeast Asia and South America). Other ACTs such as artemether-lumefantrine and artesunate-amodiaquine are generally better tolerated and are widely used in sub-Saharan Africa. As mentioned before, oral monotherapy, including with artemisinin drugs, is not recommended because of the likelihood of promoting the spread and intensification of drug resistance and has been banned by most countries.

### *Treatment of severe malaria*

Severe malaria is characterized by any one or more of the following symptoms or findings: prostration, impaired consciousness or coma, multiple convulsions (more than two within 24 hours), circulatory shock, pulmonary edema, acute respiratory distress syndrome, abnormal bleeding, jaundice, severe anemia, acute renal failure, disseminated intravascular coagulation, acidosis, hemoglobinuria, hypoglycemia, hyperlactatemia, or *P. falciparum* parasitemia greater than 10%. The definition of severe vivax malaria is the same as for falciparum, but without a parasite density threshold.

Severe malaria is a medical emergency and should be managed with the immediate initiation of appropriate parenteral treatment. Based on evidence from a large, multi-center, randomized trial, WHO modified their treatment guidelines for severe malaria in 2011 **to recommend parenteral artesunate as the first-line treatment in children and adults, including pregnant women in all trimesters; if parenteral artesunate or artemether is not readily available, parenteral quinine should be used.**<sup>103</sup> Toolkits and other helpful information about severe malaria are available at <https://www.severemalaria.org/>.

### *Severe malaria at peripheral/community level*

Management of severe malaria cases at peripheral 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 until the patient can receive parenteral therapy at a higher-level facility) and rapid referral to an appropriate health facility. NMCPs from nearly all PMI countries have incorporated rectal artesunate into their case management guidelines, although many deviate from the most recent WHO Malaria Treatment Guidelines, which recommend use only for those less than six years of age, a point reiterated in a subsequent WHO information

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<sup>103</sup> Arjen M Dondorp et al. Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. *The Lancet*. [Volume 376, Issue 9753](#), 13e 376, Issue 9753w.sciencedirect.7.



note.<sup>104</sup> 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. The WHO information note also recommends the 100-mg formulation (WHO pre-qualified products are available from two manufacturers) over the 50- and 200-mg formulations, and indicates that ‘as 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.’”

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

### *Treatment of malaria in pregnancy*

Information on this topic can be found in the **MIP** chapter.

## **Integrated Community Case Management**

A number of studies have demonstrated that malaria diagnosis and treatment can be provided to children less than five years of age through community-based agents. WHO and UNICEF recommend implementation of iCCM for sick children less than five years of age as an essential method for improving access to malaria diagnosis and treatment. The iCCM approach provides diagnosis and treatment of pneumonia, diarrhea, and malaria (including the use of RDTs) through community health workers or health extension workers using standard algorithms. Such iCCM programs also provide a platform for facilitating referral of severe illness, including use of pre-referral rectal artesunate.

Each PMI country must tailor its iCCM program to meet country needs which include decisions on location of CHWs, whether CHWs will be paid (salary/stipend or other compensation) or volunteer, and what age groups the CHWs will serve. Because access to adequate diagnosis and treatment may be difficult in many rural areas of sub-Saharan Africa, PMI encourages all focus

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<sup>104</sup> [Rectal artesunate for pre-referral treatment of severe malaria](#). WHO October 2017.

countries to develop policies and support scaling-up of iCCM programs that include diagnosis with RDTs and treatment of malaria. Where possible, PMI strongly encourages the development of a systematic approach to the collection, processing, and reporting of all testing and treatment data gathered through iCCM efforts. Data from iCCM will strengthen malaria surveillance systems and complement the routine data collected from health facilities.

### *PMI funding for iCCM*

PMI funding can be used to support integrated platform costs which include trainings; 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 diagnosis and treat three main causes of childhood fever, but that programming should be co-supported and co-funded by maternal and child health or community health partners.

**PMI funding can only be used to procure malaria commodities**, therefore funding for pneumonia and diarrhea medications must be provided by other sources. UNICEF and USAID MCH do support procurement of these commodities in some countries; however, at present, no other donor has committed to consistently buying these medicines. Thus NMCPs should discuss and collaborate with their Ministry of Health MCH and/or Community Health counterparts to encourage prioritizing domestic resources. PMI recognizes that this can unfortunately result in malaria CCM, and not an iCCM program, when these gaps in non-malaria commodities exist. PMI does not support salaries, salary top-ups, or stipends (other than stipends associated with program costs such as training and associated travel); please review the *‘Incentives and Retention Strategies for CHWs’* section below.

PMI generally supports iCCM for children younger than five years of age as recommended by WHO and UNICEF.<sup>105</sup> Several PMI countries are implementing or considering the expansion of malaria testing and treatment of older age groups by CHWs. At this time, PMI support for community case management of malaria in all ages is being considered on a case-by-case basis. Countries that are considering expanding the age range for community case management of malaria should be aware of the implications on supply chain, reporting, and increased work load for CHWs. PMI is currently supporting operational research to understand some of these implications in two countries. Please contact Kim Connolly ([kconnolly@usaid.gov](mailto:kconnolly@usaid.gov)) or Lauren Lewis ([lwb6@cdc.gov](mailto:lwb6@cdc.gov)) for more information on this issue.

More information on iCCM, including information on training, iCCM indicators, and the latest research, can be found at: [www.cccentral.org](http://www.cccentral.org). For further questions about iCCM, please contact Kim Connolly ([kconnolly@usaid.gov](mailto:kconnolly@usaid.gov)) or Lauren Lewis ([lwb6@cdc.gov](mailto:lwb6@cdc.gov)).

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<sup>105</sup> [WHO/UNICEF Joint Statement: Integrated Community Case Management \(iCCM\) 2012](#)

## Diagnosis and Treatment in the Private Sector

In many PMI-supported countries, a large proportion of malaria cases are diagnosed and treated in the private sector. The private sector often includes non-profit and faith-based clinics and hospitals, for-profit facilities and providers, licensed retail outlets (including pharmacies and drug shops), and informal providers (both at fixed sites and mobile). Appropriate use of diagnostics and treatment in this sector has the potential for significant impact on malaria control and prevention.

PMI encourages all focus country teams to work with NMCPs to assess whether intervention in the private sector should be prioritized. The first step in such assessment is to clearly define which types of providers should be targeted. In most countries, non-profit and faith-based facilities already receive support and oversight from the MOH, essentially functioning like an extension of the public health system. Other private providers may or may not be overseen by pharmacy boards or drug regulatory authorities, depending on the country. Most commonly, the target of so-called private sector interventions are registered private, for-profit facilities and providers, and/or private retail outlets, but this will vary by country. Irrespective of which private sector partners are engaged, a system of accountability for commodity supplies, quality services, biosafety, and data reporting to assess effectiveness is critical to the success of such a program. In most cases, introducing such services into the private sector will require changes to regulations related to the performance of diagnostic testing, biosafety, and diagnostic and prescribing practices. Engaging in the private sector will also have implications for training and supervision that need to be budgeted for.

As in the public sector, 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.**

Many of the challenges with providing comprehensive malaria case management services in the public sector are amplified in the private sector. Ensuring that only high quality RDTs and ACTs are available may require better monitoring and enforcement by drug regulatory authorities, intervention with importers and wholesalers, and subsidies that reduce financial barriers to retailers and consumers. Structures may also be lacking to provide appropriate training and supervision of private providers, as well as case reporting and monitoring and evaluation of program effectiveness.

There may be opportunities, though, to partner with existing private sector structures, including pharmacy and/or medical societies or associations or common wholesalers or supply networks, to identify target providers. These groups may serve as platforms to support training and

supervision. Such networks also may play a central role in the supply of quality-assured commodities to private outlets.

Unlike the public sector, where diagnosis and treatment are often provided for free or at low cost, any private sector strategy must have a clear plan on appropriate pricing of diagnostic testing and treatment that takes into account the consumer's willingness to pay, the need of retailers and suppliers to make a reasonable profit, and the market prices of non-recommended treatments. The easy availability of alternative treatments for non-malaria fevers (e.g., antibiotics and antipyretics, such as paracetamol) must be considered, as it has been shown that inappropriate use of malaria treatment can be reduced if alternative treatments are available. **Commodities procured and donated by PMI (ACTs and RDTs) cannot be sold for profit. Therefore all PMI-procured commodities must be provided free of charge to patients/beneficiaries. Where approved, when working with the private for-profit sector, PMI teams should engage the PMI Headquarters Case Management Team to ensure that PMI-supported private sector activities (using commodities procured by other sources) are in line with PMI Technical Guidance.** Finally, when working with the private for-profit sector, 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.

In addition, any private sector intervention must be accompanied by good training, supervision, and appropriate behavior change and communications activities. It should be recognized that, with the introduction of diagnostic testing, appropriate messaging becomes far more complex. Simply instructing consumers to seek treatment for fever is no longer sufficient. Rather, those with fever must be encouraged to get tested, to take treatment only if the test is positive, and to look for other causes of fever if they test negative. An analysis of 12 studies on the introduction of RDTs in the private sector is available for more information, and includes lessons learned and recommendations for consideration.<sup>106</sup>

Given these many complexities, countries are encouraged to seek the guidance of the PMI Headquarters Case Management Team early in the planning phase for such private sector interventions.

## Surveillance of Antimalarial Drug Efficacy

### *Conducting therapeutic efficacy studies (TES)*

In Southeast Asia, artemisinin resistance—which manifests as delayed clearance of parasitemia and is associated with mutations to the *k13* gene – has now been reported from multiple areas

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<sup>106</sup> Visser T et al. [Introducing malaria rapid diagnostic tests in private medicine retail outlets: A systematic literature review](#). PLoS One. 2017 12(3).

throughout the Greater Mekong Subregion.<sup>107,108</sup> Fortunately, there is no clinical evidence of similar resistance outside of the Mekong. For *P. vivax*, resistance to chloroquine is an increasing public health problem in Indonesia and Papua New Guinea. Cases of chloroquine-resistant *P. vivax* have been reported from other regions, but only in small numbers or sporadic cases.

PMI recommends that all focus countries/programs establish and maintain routine, periodic monitoring of the therapeutic efficacy of their first-line (and if possible, second-line) malaria treatment in line with WHO recommendations.<sup>109</sup> WHO recommends that the efficacy monitoring be conducted once every 24 months at four to eight sites per country, with at least 88 patients enrolled per arm per site. To help sustain the capacity of national testing teams, many NMCPs conduct such monitoring at half the sites one year and the other half the following year. The maximum cost to conduct such surveillance should be up to \$75,000 per site per year, with the potential for exceptions based on in-country justification. Second-line treatments can also be included in the testing. The WHO standard protocol is not designed for the evaluation of new or experimental medicines.

The purpose of antimalarial drug efficacy surveillance is to allow ministries of health to develop or update national treatment strategies and policies, and facilitate a timely change to a new first-line antimalarial, if necessary. PMI need not financially support the full cost of all *in vivo* studies, as many countries will have other sources of funding for these studies. In those cases, PMI can provide technical assistance when needed to ensure that these data are of high quality, and interpreted and used appropriately. To facilitate high quality data collection in therapeutic efficacy studies (TES) that are PMI-funded or not, PMI has piloted a (QA)/quality control (QC) checklist and protocol for assuring high quality data collection and is currently working with country teams with planned TES to implement the checklist. The goal is a simple, rapid QA tool that can be implemented in TES across PMI-supported countries, and thereby assure some consistency of data quality across countries. For further information, please contact the TES/ PMI Antimalarial Resistance Monitoring in Africa (PARMA) team (Eric Halsey ([ycw8@cdc.gov](mailto:ycw8@cdc.gov)), Leah Moriarty ([wvp4@cdc.gov](mailto:wvp4@cdc.gov)) or Meera Venkatesan ([mvenkatesan@usaid.gov](mailto:mvenkatesan@usaid.gov))).

PMI should work with NMCPs to ensure the sharing of drug efficacy data with WHO, Worldwide Antimalarial Resistance Monitoring Network, and international consortia focusing on antimalarial drug resistance.

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<sup>107</sup> Ashley EA et al. [Spread of artemisinin resistance in Plasmodium falciparum malaria](#). *N Engl J Med*. 2014 Jul 31;371(5):411-23

<sup>108</sup> WHO status report April 2017: [Artemisinin and artemisinin-based combination therapy resistance](#)

<sup>109</sup> [http://whqlibdoc.who.int/publications/2009/9789241597531\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241597531_eng.pdf)

## *Using TES results for selection of treatments*

According to WHO guidelines, the first-line antimalarial treatment should be switched to another more effective alternative if therapeutic efficacy falls below 90%. Although ACT efficacy is generally high (>95%) in sub-Saharan Africa, there have been reports of some combinations reaching or exceeding 10% treatment failures in certain sites, likely due to resistance or tolerance to the partner drug. Please contact the TES/PARMA team with any concerns about TES results, their interpretation, and any follow up actions.

## **Monitoring Molecular Markers of Antimalarial Resistance**

### *Introduction*

Studies have identified<sup>110</sup> and validated<sup>12</sup> a strong association between prolonged parasite clearance and point mutations in the propeller region of the *P. falciparum* kelch protein on chromosome 13 (K13). PMI support for K13 monitoring allows PMI to pick up any early signs that resistance is emerging or spreading before in vivo resistance becomes apparent. Molecular markers of resistance to piperazine<sup>111,112</sup> have also been detected in Southeast Asia, and markers linked to tolerance of other partner drugs have also been identified.<sup>113</sup>

The PARMA Network has been established to determine when artemisinin resistance-conferring mutations in the *k13* gene arise or appear in Africa. PMI also monitors molecular markers for resistance to ACT partner drugs, as appropriate. These include markers for lumefantrine and piperazine and, starting in 2019, SP, which is used primarily in IPTp and SMC. Activities of the network will supplement countries' routine drug efficacy monitoring efforts by characterizing molecular markers that may help to improve surveillance by adding genetic information to the clinical outcome data already generated by the study. In addition to the expedient testing of TES samples for the presence of molecular markers of antimalarial resistance, PMI also prioritizes training appropriate country laboratory staff in these techniques. Sample collection for molecular testing is now being carried out in fourteen countries, and many more are anticipated to join the network in the upcoming year. Beginning with FY 2018 funds, expenses related to capacity-building visits to CDC/Atlanta (i.e., a laboratory worker from the TES country learning the techniques and testing samples during a 8-week visit to the CDC) should be included in MOPs at an estimated \$12,000 per trainee, if the country prioritizes this for funding. Ideally, the PARMA trainee will already possess a background in malaria laboratory techniques and be affiliated either with the national malaria control program or a well-established malaria laboratory. Once

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<sup>110</sup> Arley F et al. [A molecular marker of artemisinin-resistant \*Plasmodium falciparum\* malaria](#). 2014. *Nature*. 505(7481):50-5.

<sup>111</sup> <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2816%2930409-1/fulltext>

<sup>112</sup> <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2816%2930415-7/fulltext>

<sup>113</sup> <http://www.ajtmh.org/content/91/4/833.long>

this initial training visit is accomplished, the aim is for future TES-related lab work to occur in-country (a CDC Malaria Lab expert can offer on-site support) or at an Africa-based “regional PARMA hub.” The PARMA headquarters team has currently identified 2-3 countries that may act as a regional PARMA hub and are in the process of arranging initial visits. The PARMA headquarters team is working closely with individual country teams to assess the current status of in-country efficacy testing and how best to plan and budget for activities. Standard operating procedures covering sample collection, storage, and shipment are available upon request. Questions can be directed to the TES/PARMA team at PMI Headquarters.

### *Sampling framework*

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

Dried blood spot samples for *k13* genotyping will be collected on filter paper following the WHO protocol for sample collection for recrudescence/reinfection genotyping. Blood spots should be collected on day 0 and on every subsequent day of follow-up. Spots already being collected for testing recrudescence versus reinfection should provide sufficient material for both K13 and recrudescence/reinfection genotyping. Detailed protocols for collection, labelling, storage, and shipment of specimens are in place and can be shared upon request.

### *k13 genotyping methodology and analysis*

Because there is a diversity of point mutations within the *k13* propeller region and it is not yet fully known which point mutations may be relevant for artemisinin resistance, WHO and PMI recommend sequencing the entire propeller region of the kelch gene. This activity will be carried out by the molecular laboratory at the CDC Malaria Branch in Atlanta, or, in some cases, by laboratories in country that are already conducting *k13* testing. Molecular marker resistance testing for other antimalarials—such as lumefantrine, amodiaquine, and SP—is also routinely done in the CDC Malaria Laboratory during PARMA visits. All resistance data generated at the CDC laboratory will be analyzed and the in-country study investigators will be encouraged to share results within the country (with NMCP and others as appropriate), as well as with WHO. Broader sharing with groups such as the Worldwide Antimalarial Resistance Network is encouraged. 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.

# Forecasting, Procuring, Distributing, and Monitoring the Quality of Drugs and Diagnostics

## *Forecasting*

Forecasting requirements for ACTs and RDTs must be done in tandem and informed by available country data. Although accurate consumption data is best used for this purpose, in many PMI-supported countries these data are not available or they are of poor quality. In such situations, forecasts can be developed using morbidity data. RBM, with the support of PMI, has detailed guidance on the quantification of ACTs and RDTs that should assist countries in developing more accurate estimates of country needs.<sup>114, 115</sup> Because many countries are now scaling up RDT use in peripheral health facilities and at the community level, it is critical to take into account the country's policies on diagnostic testing, in particular where and in what situations microscopy and/or RDTs are to be used, when quantifying these requirements. Refer to the **Commodity Procurement** and **Supply Chain Management** chapters for further information on quantification.

## *RDT selection*

WHO, in collaboration with the Foundation for Innovative New Diagnostics (FIND) and CDC, has conducted eight rounds of standardized product testing and prepared an information note on criteria for selecting appropriate tests.<sup>116</sup> In addition, an interactive web-based tool is available to assist countries in choosing RDTs based on preferred characteristics. As there are currently more than 200 different brands of RDT kits available on the market, the choice of the appropriate RDT kit should be decided by each country based on their specific needs. These tests are relatively easy to use following only a few hours of appropriate, high-quality training, but ongoing supportive supervision is necessary. RDTs come in a number of formats, including strips, cards, and cassettes. In general, the cassette format has been demonstrated to be easier to use than other formats. Different RDT kits have different accessory components, including different blood handling devices, and somewhat different procedures (e.g., different numbers of drops of buffer, different incubation times). In general, the shelf-life of RDTs is approximately 24 months from the date of manufacture. If more than one RDT brand with different characteristics is used in a country, it is important that adequate information is provided to health workers about how the tests differ. Where relevant, PMI country teams should work closely with NMCPs and other

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<sup>114</sup> [Good practices for selecting and procuring rapid diagnostic tests for malaria:](#)

<sup>115</sup> [Manual for quantification of malaria commodities: Rapid diagnostic tests and Artemisinin-based combination therapy for first-line treatment of \*Plasmodium falciparum\* malaria](#)

<sup>116</sup> [Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests \(RDTs\)](#)



donors to harmonize procurements and trainings to ensure that health care workers have been trained on the key steps for the RDTs that are being purchased.

All RDTs procured by PMI undergo pre-shipment lot testing to assess their quality prior to delivery. Extensive experience from multiple countries and results from lot testing indicate that RDTs are much more stable to temperature and humidity extremes than originally thought. PMI has rarely identified RDTs of poor quality before or after distribution. For information on post-deployment lot testing, please see Priority Area #4 below (“Quality assurance of diagnostic testing”). In recent years, reports were received regarding the failure of nine different single use test kits, sourced from three manufacturers. Specifically, reports indicated buffer evaporation from the individual ampules, rendering the RDT unusable. Through collaboration with the WHO GMP, a root cause was identified and resolved.

It is important to provide training and capacity building among healthcare practitioners and staff to collect an appropriate blood sample, conduct the test, and be able to identify tests with problems that affect performance. RDTs are not designed to determine the density of parasitemia, which is required for monitoring the response to treatment for severe malaria. As with microscopy, testing also produces biohazardous waste that must be properly disposed in accordance with national guidelines. For information on temperature monitoring to ensure RDT stability, please see Priority Area #4 below.

### Multi-species tests

Some NMCPs in PMI-supported countries have indicated an interest in procuring RDTs that detect both *P. falciparum* and other Plasmodium species, so-called multi-species RDTs. Many of these RDTs have been shown to accurately detect both *P. falciparum* and *P. vivax* and are recommended by WHO for use in “Zone 2” countries with significant falciparum and vivax malaria, including Ethiopia, Madagascar, and the Greater Mekong Subregion.<sup>15</sup> The remaining PMI-supported countries are classified as “Zone 1” (*P. falciparum*-predominant), where WHO recommends that single-species tests be used. A growing number of Zone 1 countries have requested that PMI procure multi-species RDTs, including Pan/Pf RDTs, with a rationale that NMCPs also want the capacity to diagnose non-falciparum species (which in such settings would be largely *P. malariae*). However, only a limited number of studies are available and these have shown the accuracy of RDTs to detect *P. malariae* is rather poor<sup>117</sup>, which is at least partly explained by the very low parasite density of most *P. malariae* infections. Moreover, 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 Pf-only infections.

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<sup>117</sup> [A Systematic Review: Performance of Rapid Diagnostic Tests for the Detection of \*Plasmodium knowlesi\*, \*Plasmodium malariae\*, and \*Plasmodium ovale\* Monoinfections in Human Blood](#)

Beyond the technical aspects on which WHO bases these recommendations, there also are programmatic considerations that further strengthen this guidance. Single species RDTs are simpler to interpret (as there is only one test line and one control line) and they are less costly. The unit cost of multi-species RDTs is up to 30% greater than single-species RDTs. Based on the WHO guidance, reviewing species prevalence data from selected countries, and assessing the cost implications of procuring single vs. multi-species RDTs, **PMI no longer supports procuring multi-species RDTs in countries that WHO classifies as Zone 1 (*P. falciparum*-predominant). All PMI-supported countries in Africa (with the exception of Madagascar and Ethiopia) should be procuring single-species *P. falciparum* RDTs.**

Exceptions to this guidance will be granted if credible evidence can be provided to PMI leadership that demonstrates ongoing local transmission of *P. vivax* infections of significant prevalence (at least 5% relative prevalence).

#### *hrp2 deletions and multi-antigen tests*

As reported in an information note published by WHO<sup>118</sup>, malaria parasites lacking the HRP2 and/or HRP3 antigens (the antigens detected by current *P. falciparum* RDTs) have recently been identified in Sub-Saharan Africa. Parasites with *hrp2/hrp3* gene deletions were first detected in the Peruvian Amazon and have since been identified in various locations in South America as well as in India.

In 2016, such deletions were documented at high prevalence in areas of Eritrea, near the border with Sudan. Different research groups have reported detection of deletions in DRC, Mali, Uganda, Rwanda, and Ghana, but the methods used and reliability of these reports are variable. It should be noted that RDT failure can have multiple causes, including user error and poor efficacy due to inappropriate storage conditions, in addition to *hrp2/hrp3* deletions.

Starting in 2019, the CDC Malaria Laboratory can test TES samples (i.e., those brought to CDC Atlanta as part of PARMA) for the presence of *hrp2/hrp3* gene deletions. This analysis will still have to be endorsed by the NMCP and TES principal investigator and covered in the study protocol. This assessment is available to all PMI countries, regardless of whether or not the country (or adjacent countries) have reported cases of *hrp2* deletions. However, if TES samples are used, then TES subjects should not be excluded based on an HRP2-based RDT.

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<sup>118</sup> [False-negative RDT results and implications of new reports of \*P. falciparum\* histidine-rich protein 2/3 gene deletions](#)

If *hrp2/hrp3* deletions are detected, or if there is a reason to suspect deletions, then follow-up investigations may be warranted, using a WHO protocol<sup>119</sup> specifically designed to characterize the prevalence of this deletion in a given region.

PMI will work with countries with suspected/reported *hrp2* deletions and their neighbors to implement surveillance and will continue to share guidance from WHO as it is developed. Countries that either have evidence of *hrp2*-deleted parasites or that suspect that such deleted parasites exist in their countries should contact the PMI Headquarters 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.

Current options for non-*hrp2* based RDTs include tests that detect two *P. falciparum* antigens (HRP2 and LDH) with two different result lines (which can be complicated to interpret in a programmatic setting), with both antigens on the same line (which is preferable for a programmatic setting), and single Pan-LDH or Pf-LDH antigens.. These RDTs were included in testing against parasites with *hrp2* gene deletions in Round 8 of WHO product testing, completed in 2018. Two Pan-LDH RDTs met the procurement criteria, and none of the Pf-specific RDTs (Pf-LDH with or without HRP2) met the procurement criteria. Thus, at this time, RDT options for regions with *hrp2* deletions remain limited and imperfect.

Please reach out to the following members of the PMI Headquarters Case Management Team for further information: Meera Venkatesan (mvenkatesan@usaid.gov), Leah Moriarty (wvp4@cdc.gov), or Eric Halsey (ycw8@cdc.gov).

### *Quality monitoring of drugs*

Quality monitoring of drugs available in public and private sector outlets has been supported by PMI in many focus countries. These programs monitor the quality and availability of antimalarial drugs using tools such as market surveys and mystery shopper assessments. PMI, through its implementing partners, collects readily available public and private sector antimalarial products and sends them for quantitative analysis at qualified laboratories to determine content and quality. Drug registration processes also are evaluated. These activities help national drug regulatory authorities on multiple levels, including improving and strengthening technical capacity and overall quality assurance.

PMI strives to strengthen existing quality control measures, thereby helping develop more robust quality assurance programs overall. When part of a larger strategic plan and longer-term strategy where the primary objective is to build a robust national-level quality assurance program, country teams are encouraged to invest in drug quality monitoring programs and should take into

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<sup>119</sup> [Protocol for estimating the prevalence of pfhrp2/pfhrp3 gene deletions among symptomatic falciparum patients with false-negative RDT results](#)

consideration information from various PMI or USAID Global Health-supported technical assistance.

For more information on drug quality, please refer to the **Commodity Procurement and Supply Chain Management** chapters.

## Priority Areas for PMI Support

A successful malaria case management program consists of several distinct but interrelated activities that should be implemented in concert.

1. **Appropriate policies and guidelines:** WHO has published detailed guidance for laboratory procedures for malaria diagnosis and on the programmatic elements of a malaria diagnostics program, which should assist the development of national policies and guidelines.<sup>120, 121, 122</sup> These documents also provide specific guidance on the type of test (microscopy or RDT) that is appropriate at different levels of care, how to select an appropriate RDT for specific epidemiologic contexts, and which RDT kits are recommended for use.

Policies and guidelines on the clinical management of fever and malaria should be periodically reviewed, revised, and harmonized with WHO recommendations<sup>1</sup> and other relevant clinical policies and guidelines (e.g., integrated management of childhood illness guidelines). These policies and guidelines 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 and job aides on performing the test and guidance on handling and disposal of blood and biohazardous materials.

Policies on drug treatment for malaria should periodically be reviewed to ensure they are in line with WHO recommendations. They also should be informed by the results of the latest TESs and other relevant investigations (e.g., acceptability studies). In particular, policies regarding treatment of severe malaria should be aligned with the updated recommendations issued by WHO in 2015.<sup>1</sup> In countries with co-endemic vivax malaria, treatment strategies should be species-specific for the treatment of

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<sup>120</sup> WHO Malaria Diagnosis website: <http://www.who.int/malaria/areas/diagnosis/en/>

<sup>121</sup> [Universal Access To Malaria Diagnostic Testing: An operational manual](#) 2011:

<sup>122</sup> [Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 8 \(2016-2018\)](#)

uncomplicated malaria and for malaria in pregnant women with a strategy for preventing relapses. Such guidance should clearly articulate when treatment is to be provided, at what level of care, what facilities and supportive services are required, and when referral is indicated. Policies and guidelines also should clearly articulate what is and what is not permissible for both diagnosis and treatment at community level and in the private sector and the qualifications and training required for CHWs and private providers.

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 who may not be authorized or trained to conduct these tests. In the private sector, the most common sources of malaria treatment may be drug dispensers, who may be restricted from performing diagnostic tests or dispensing drugs without a prescription. In some countries, this may require changes in legislation. Teams are encouraged to work with NMCPs as they develop or update national case management guidelines. PMI Headquarters has developed a checklist that can guide this process. Please contact Eric Halsey ([ycw8@cdc.gov](mailto:ycw8@cdc.gov)) or Meera Venkatesan ([mvenkatesan@usaid.gov](mailto:mvenkatesan@usaid.gov)) for this tool.

- 2. Training and supervision of laboratory staff:** In most countries, training and supervision of laboratory personnel will be delivered as an integrated package. It is the responsibility of the NMCP, the National Reference Laboratory, and/or the Laboratory Department of the MOH to ensure that training materials reflect the current state-of-the-art, that the trainers and supervisors have the appropriate level of skill in the performance of malaria microscopy and RDTs, 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 in both RDTs and microscopy when supervision identifies deficiencies in health worker performance of the test. Training and supervision materials, SOPs, and bench aids developed by PMI through the MalariaCare Project<sup>123</sup> can be adapted and tailored to country context. The CDC malaria diagnostics bench aids and SOPs are available on the CDC DPDx website (<http://dpd.cdc.gov/dpdx/Default.htm>). In addition, a CDC-developed malaria microscopy training CD-ROM (in English) can be obtained from WHO Global Malaria Programme at: [http://www.who.int/malaria/areas/diagnosis/microscopy\\_cd\\_rom/en/](http://www.who.int/malaria/areas/diagnosis/microscopy_cd_rom/en/)

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<sup>123</sup> [Malariacare Toolkit](#)

3. **Training and supervision of clinical staff:** Training curricula for clinicians and community health workers should be periodically revised to align with the country's most updated malaria case management policies and guidelines, including integrated management of childhood illness guidelines. Whenever feasible, clinical training on malaria case management should be incorporated into training on the management of childhood illness. In addition, experience suggests that coordinated training of clinical and laboratory staff, in those facilities with laboratories, improves clinicians' understanding and interpretation of the results of diagnostic testing. After training, periodic supportive supervision of clinicians and community health workers will be required. When possible, such supervision should be built into existing functional supervisory mechanisms, be 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. A tool kit for iCCM is available on the CCM Central website ([www.ccmcentral.org](http://www.ccmcentral.org)).
  
4. **Quality assurance (QA) of diagnostic testing:** Development of a QA system is an essential component of a comprehensive diagnostics program. WHO has developed detailed guidelines on quality control of malaria microscopy,<sup>124</sup> which involves collection of a subset of slides from clinical specimens and re-examination of those slides by expert microscopists, which depending on country situation can be performed during a supervision visit or in a national, regional, or district reference laboratory. PMI supports the development or purchase of validated malaria reference slide sets with known species and parasitemia density that can be used for training and quality assurance. On average, the development of a national archive of malaria microscopy slides costs \$100,000, including costs associated with seeking ethical approvals, training, sample collection, validation, and supplies. Because multiple slides are produced during the activity, providing a wide and redundant range of parasitemia and species combinations (as applicable), this is largely a one-time expenditure for countries. 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 country.

At this time, methods for quality control of RDTs at the point-of-service are somewhat limited, but must be considered. Facility- and community-level QA/QC should include, at a minimum, regular supervision at least every six months with observation of healthcare workers' performance of RDTs using a standardized checklist. Laminated cards with pictures of positive, negative, and invalid RDT results also have been used to test health workers' skill at interpreting test results. Positive control wells (PCWs) with positive control antigens that enable end-users to determine whether the RDT kit

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<sup>124</sup> [Malaria microscopy quality assurance manual - version 2](#)

they are using is performing properly are now available from a limited number of manufacturers for a limited set of products. WHO is in the process of developing guidance on how these PCWs should be used and by whom. Although PMI is not currently supporting the use of PCWs, further guidance on the appropriate piloting/use of PCWs will be issued once they are available for procurement. The following activities for QA of RDTs are **not recommended**: cross-checking RDTs with blood slide microscopy, saving RDTs for re-reading, or conducting PCR as part of clinical case management.

Rapid diagnostic tests require proper transport and storage to avoid damage that may be caused by extreme heat and humidity. Post-deployment monitoring of RDT kit performance can be conducted in cases where storage conditions are known or suspected to be poor. 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, testing 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. WHO and PMI do not recommend routinely comparing microscopy to RDT performance, as they measure different evidence of infection (RDTs detect parasite antigen, microscopy detects actual parasites). Such a comparative assessment, though, may be useful as a first step in an investigation of suspected poor quality RDTs.

WHO updated its guidelines for QA of malaria microscopy, in January 2016 and it can be accessed at this link:

<http://www.who.int/malaria/publications/atoz/9789241549394/en/>.

5. **Equipment and supplies:** For microscopy, lists of necessary supplies and specifications for microscopes are widely available through WHO, CDC, and from PMI headquarters upon request. The choice of RDT will be made by each NMCP, based on their specific needs, and should be informed by the WHO-FIND RDT product testing program and the most recent version of the Information note on criteria for RDT selection.<sup>17</sup>

For both RDTs and microscopy, it is essential that proper supplies for blood sampling and for the safe disposal of biohazardous materials – including latex gloves, sharps boxes, and cleaning materials – are also available wherever testing is done. In addition, supplies for maintaining and monitoring proper storage temperature, such as thermometers, may be needed. In most countries, procurement of laboratory supplies is handled by the same authorities that handle pharmaceuticals. In others, the central laboratory or individual regional or district authorities may handle procurement and/or distribution. In many cases, local quality-assured sources of these supplies may be

procured more quickly and at lower cost than through the PMI central supply chain partner.

Correct quantifying of needs for ACTs, RDTs, and laboratory supplies has been a significant challenge in all PMI-supported countries because of the lack of complete and accurate consumption data for these product. See the '*Forecasting, Procuring, Distributing, and Monitoring the Quality of Drugs and Diagnostics*' section above for further information on quantification tools. Support is provided to partners for improving the capacities of the NMCPs and other key stakeholders in the quantification of requirements for these commodities. Guidance on quantification can be found in the **Commodity Procurement and Supply Chain Management** chapter.

6. **Communications and behavior change:** 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. Scale-up of diagnostic testing, therefore, poses a major communications and behavior change challenge, particularly for health workers, but also for caretakers of sick children who have a negative test and do not receive treatment for malaria. Diagnostic testing must be closely linked with communications and behavior change activities focused on changing the expectations and practices of patients and caregivers. In addition, the availability of poor quality, counterfeit, and inappropriate drugs (including artemisinin monotherapy and older treatments, such as chloroquine) requires that behavior change and communications messages and activities also focus on promoting use and adherence to recommended quality-assured ACTs.
7. **Incentives and retention strategies for CHWs:** This remains a controversial area, although there is a growing consensus that some incentives are needed to retain CHWs. Incentives can range from needed supplies and equipment, such as flashlights, bicycles, and funds for travel, to stipends or salaries. Each country will decide, based on all relevant factors, what is the best approach for their community workers. There is a growing body of experience in a number of countries with the use of various types of incentives. In general, PMI does not provide support for monetary incentives for CHWs beyond reimbursement of travel or other expenses. Support for other incentives (e.g., bicycles, flashlights, etc.) may be appropriate in some situations and settings. For more information on incentives, refer to the new *WHO guideline on health policy and system support to optimize community health worker programme*.  
<https://apps.who.int/iris/bitstream/handle/10665/275474/9789241550369-eng.pdf?ua=1>



## Frequently Asked Questions for Diagnostic Testing

### **Q1. What can be done to improve the accuracy of malaria diagnosis?**

**A.** For both RDTs and microscopy, a QA system should be established to monitor accuracy of test performance. The QA system should include, but not be limited to, appropriate training, regular on-site supervision to monitor adherence to standard operating procedures and test performance, and proficiency testing. Procurement of quality tests, supplies and reagents, and storage temperature monitoring should be part of a comprehensive QA system.

### **Q2. Should PMI countries invest in post-deployment lot testing of RDTs?**

**A.** Post-deployment monitoring of RDT kit performance can be conducted in cases where storage conditions are known or suspected to be poor, or if there is evidence of RDTs failure in a clinical setting. 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, however, testing should be performed no sooner than 12 months post-deployment. Through December 2019, samples of test kits should be sent to the WHO/GMP-approved laboratory facility in the Philippines for further lot testing. PMI is in discussion with WHO and others regarding plans for RDT lot quality control testing going forward in early 2020.

### **Q3. How can countries encourage the use of diagnostic test results for treatment decisions?**

**A.** With both RDTs and malaria microscopy, several studies have demonstrated that clinicians may not always accept negative test results when those results do not agree with their clinical impression of the cause of a patient's illness. Recent evaluations, though, demonstrate that good training, supervision, and the use of job aids, plus training and equipping providers to manage non-malaria fevers, improves health workers' adherence to the test results. Implementation of a strong quality assurance plan also improves clinician acceptance and use of test results. Interestingly, CHWs tend to adhere to test results much more frequently than higher-level health workers. This is probably because CHWs training and supervision is heavily focused on adherence to established case management algorithms.

### **Q4. For countries with co-endemic *P. vivax*, how and when should one test for glucose-6-phosphate dehydrogenase deficiency?**

**A.** Glucose-6-phosphate dehydrogenase (G6PD) deficiency, an X-linked chromosomal disorder, is the most common enzymatic disorder of red blood cells in humans, affecting more than 400 million people worldwide. The prevalence of G6PD mutations is highest in populations residing in regions that are historically malaria endemic. Individuals with severe G6PD deficiency cannot tolerate the cellular oxidative stress caused by 8-aminoquinoline drugs, such as primaquine and

tafenoquine. Prior to primaquine administration for vivax radical cure, which is currently the only registered drug available for radical cure of *P. vivax* hypnozoites in PMI countries, patients should undergo G6PD testing as per their national treatment guidelines. No G6PD testing is required, however, for single, low-dose (0.25mg/kg) primaquine use.

In most clinical settings, a qualitative method (most often the fluorescent spot test) is used to guide primaquine administration but requires additional equipment and training and is not suitable for point-of-care use. Two products are currently marketed for point-of-care use, BinaxNOW® G6PD and the CareStart™ G6PD deficiency screening test. The BinaxNow G6PD test is US FDA approved, but has not been used widely due to its requirement for venous blood collection, strict temperature range of 18°C to 25°C, and high cost of around \$25 per test. The CareStart G6PD deficiency screening test is a qualitative enzyme chromatographic test that uses blood from a finger prick and has shown test performance comparable to the fluorescent spot test in study settings. However, wide scale uptake has been limited by difficulties in interpreting a faint color change without a control line. Laos and Cambodia are planning to pilot the use of the CareStart RDT to guide primaquine treatment.

Several point-of-care G6PD tests, both quantitative and qualitative are currently under development. Manufacturers are currently planning FDA and/or WHO PQ submission.

For information on tafenoquine, a new drug for radical cure of vivax malaria that will also require a quantitative G6PD test, see FAQ 1B below.

## Frequently Asked Questions for Malaria Treatment

### **Q1. What new drugs are expected to be introduced or are in the pipeline for the treatment of malaria?**

**A. Artesunate-Pyronaridine (ASPy):** Developed under Medicines for Malaria Venture in partnership with Shin Poong Pharmaceutical Company, it received approval by the European Medicines Agency in February 2012 and added to the WHO prequalification list of approved medicines in May 2012. ASPyr is not currently on the WHO Standard Treatment Guidelines list, but is under review for potential inclusion in the updated Guidelines expected for release in September 2019. Marketed as Pyramax®, it is another fixed-dose combination, once-daily, three-day treatment regimen demonstrating efficacy against both *P. vivax* (blood stage only) and *P. falciparum*. ASPyr is available in tablet form for dosing individuals 15 kg or greater (180 mg pyronaridine/60 mg artesunate), and in a granulated formulation for children weighing 5 kg to 14 kg (60 mg pyronaridine/20 mg artesunate). Both formulations currently have a 24-month shelf-life, typical for most of the currently available ACTs, although completion of on-going stability studies are pending and are expected to extend Pyramax's shelf-life to 36 months.

Although Pyramax® has shown an acceptable safety profile, acute, reversible increases in liver enzymes were detected in some patients in early studies. Published in April 2018, data from the WANECAM two-year phase IIIb/IV study conducted in three African countries evaluated the tolerability and efficacy of Pyramax along with three other ACTs, and in a subset, the impact on QT prolongation.<sup>125</sup> Findings showed some mild elevations of hepatic enzymes but no increased risk of liver injury subsequent to retreatment, and no proarrhythmic potential from Pyramax.<sup>126</sup> A phase IV study, CANTAM, is underway in five African countries to evaluate the safety of Pyramax in the community setting. Interim data are expected at the end of 2019.

Pyramax® is registered in more than two dozen countries and already part of recently revised national treatment guidelines for three countries including Cote d'Ivoire and Niger. ASPyr can be included in PMI-supported TES testing in countries where it is included in the national guidelines or being considered for inclusion. Please reach out to Eric Halsey or Meera Venkatesan on the HQ Case Management team with any questions.

**B. Tafenoquine:** Developed in partnership between Medicines for Malaria Venture (MMV) and GSK, in 2018, tafenoquine received approval by the US FDA for single-dose use for the radical cure (prevention of relapse) of *P. vivax* malaria in patients 16 years of age and older (marketed by GSK under the brand name Krintafel), and subsequently for prophylaxis in patients 18 years of age and older (marketed by 60 Degrees Pharmaceuticals under the brand name Arakoda). Tafenoquine also has approval for the same indications by the Australian Therapeutics Good Administration (TGA). Both the US FDA and TGA will help facilitate registration in countries where malaria is endemic and will serve as the reference regulatory authorities. Although two Phase III (DETECTIVE and GATHER) trials have been completed, additional studies including in pediatric populations are still underway, including a single-arm prospective study in patients six months to < 16 years of age, in Thailand, Vietnam and Colombia. Completion is expected at the end of 2019. Medicines from the 8-aminoquinoline class, including tafenoquine and primaquine, are associated with hemolytic anemia in individuals with G6PD deficiency. 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. See Q4 under the diagnostics FAQ for more information on point-of-care tests to identify individuals with G6PD deficiency and ensure well-tolerated and effective use of medicines for radical cure of patients infected with *P. vivax*.

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<sup>125</sup> Sagara I, et al. Pyronaridine–artesunate or dihydroartemisinin–piperaquine versus current first-line therapies for repeated treatment of uncomplicated malaria: a randomised, multicentre, open-label, longitudinal, controlled, phase 3b/4 trial *Lancet* 2018; 391: 1378-90.

<sup>126</sup> Funck-Bretano C, et al. Evaluation of the effects on the QT-interval of 4 artemisinin-based combination therapies with a correction-free and heart rate-free method. *Nature* 2019; 9(8): <https://doi.org/10.1038/s41598-018-37113-5>

In addition to these two new treatments, 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 2020 MOP planning:

- **Artefenomel (OZ439) (Phase 2b):** While OZ439, a fully synthetic novel peroxide drug, is thought to act against the parasite in the same way as the artemisinins, its structural properties and *in vitro* data suggest that OZ439 is effective against artemisinin resistant strains of malaria. Phase IIb combination trials with a long-acting partner, ferroquine, are underway in seven countries.
- **KAE609 (Phase 2):** KAE609, now known as cipargamin, is a novel, synthetic antimalarial molecule belonging to the spiroindolone class, which has demonstrated an adequate pharmacokinetic and safety profile in humans. As a result, KAE609 was the first molecule with a novel mechanism of action to successfully complete Phase IIa studies for malaria in the last 20 years. Because it appears that resistance develops easily to this medication, it will most likely require dosing with another antimalarial.
- **KAF156 (Phase 2b):** KAF156, now known as ganaplacide, is the first compound from a novel class of drugs called imidazolopiperazines whose mechanism of action is still being characterized. A Phase IIa study conducted in Thailand and Vietnam showed high efficacy against *P. falciparum* and *P. vivax* infections, including artemisinin-resistant *P. falciparum* strains. Phase IIb trials are underway in combination with a new once-per-day formulation of lumefantrine in various doses, regimens, and age groups.

**Q2. What is the role of single, low-dose primaquine and hsRDT for *P. falciparum*?**

A. Please see the **Elimination** chapter (*‘Case Management’* section) for guidance on single, low-dose primaquine and updates on hsRDTs

**Q3. If my country is experiencing an increase in reported malaria cases, what is the best way to communicate that this is unlikely due to artemisinin resistance?**

A. If concerns over artemisinin resistance arise, country teams are encouraged to reach out to the PMI Case Management Team.

**Q4: What is Artequick?**

A: Artequick is an ACT (artemisinin 62.5mg + piperazine 375mg) produced by a Chinese pharmaceutical company that is not approved by WHO. Many PMI countries in Africa (e.g., Uganda, Malawi, Zambia) have reported Artequick donation offers made by a Chinese university. Comoros applied a large donation of Artequick to a comprehensive, nearly island-wide MDA campaign. Countries are often encouraged to use the donated Artequick as part of MDA, even when the transmission setting is not appropriate for MDA. In addition to the MDA-related issue, WHO (along with PMI) is concerned because of the unproven efficacy, possible

side effects, and lack of quality assurance of this medication. If teams become aware of Artequick donation offers in their country, they are encouraged to contact the PMI Case Management Headquarters team, which has already been in contact with WHO about this issue.

**Q5: Is there evidence that multiple first-line therapies (MFTs) or pre-emptive rotation of treatments should be used to prevent emergence of resistance?**

A. Currently, there is insufficient evidence for advocating for the use of multiple first-line therapies (MFTs) or pre-emptive rotation of antimalarials in Africa, with the goal of delaying or preventing the emergence of antimalarial resistance. Although some modeling results have indicated that MFTs may be effective at delaying the emergence and spread of antimalarial resistance where it has not yet developed, overall results have been mixed. With the additional consideration that the implementation of MFTs would result in higher costs and increased challenges with the supply chain, health care worker training, and SBC, WHO and PMI do not recommend employing MFTs to mitigate the development of antimalarial resistance at this time. Pilots are currently underway with support from other donors to further evaluate the strategy of MFTs, and PMI will review the results and when they are available. In parts of the Mekong with existing high levels of ACT resistance or evidence that it is developing, periodic switching of first-line therapies is used as a treatment and resistance management strategy.

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# HEALTH SYSTEMS STRENGTHENING

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

**PMI continues to contribute to strengthened health systems through PMI's support for bringing and keeping at scale proven interventions.** Capacitated health care workers and systems that deliver health services at facility and community level are necessary for continued progress in malaria control. Thus, PMI's investments across MOP technical intervention areas, not just as described in this section, contribute to health systems strengthening.

Peace Corps and Field Epidemiology Training Program (FETP) investment information are included under this section.

## **Introduction**

Building capacity and strengthening health systems is identified in the *PMI Strategy 2015-2020* as a core area of strategic focus, which states that successful country-owned and country-lead malaria control programs are only possible when country programs possess appropriately-skilled human resources and the necessary infrastructure to plan, implement, and monitor progress of their malaria control activities. In addition, “working ourselves out of jobs” is one of USAID Administrator Mark Green’s highest strategic priorities. Therefore, it is within PMI’s mandate to build capacity to enable countries to implement their own programs (rather than building parallel or stand-alone systems), including engaging communities to participate in malaria control and addressing gaps in country health systems in the key areas of supply chain management, training and supervision of health workers, health financing systems, and monitoring and disease surveillance systems.

Most, if not all, PMI-supported activities – whether intervention-specific or cross-cutting – contribute to strengthening one or more of the six internationally recognized core HSS functions of human resources for health; health finance; health governance; health information; medical products, vaccines, and technologies; and service delivery. Examples include, but are not limited to, the following:

- Strengthening quantification methods and supply chains for essential malaria commodities
- Expanding the availability of key health services by building networks of trained community health workers
- Improving the quality of facility based health services, including capacity for effective malaria diagnosis and treatment
- Improving the quality of clinical laboratory services

- Establishing and building skilled capacity for entomological monitoring
- Streamlining and expanding routine health information systems to ensure collection, transmission, analysis, and dissemination of critical malaria indicators
- Strengthening the capacity of NMCPs and local government entities to plan and oversee malaria

PMI's support for HSS is aligned with USAID's *Vision for Health Systems Strengthening 2015-2019*,<sup>127</sup> which defines four strategic outcomes to achieving **universal health coverage** (defined as a condition where all the people who need health services receive them without financial hardship):

1. **Financial protection:** reducing financial barriers to access life-saving services for the poor
2. **Essential services:** ensuring that priority maternal, newborn, infectious disease services, etc., are included in the national essential benefits packages
3. **Population coverage:** attaining coverage for people in the bottom wealth quintile and for other marginalized people
4. **Responsiveness:** improving the satisfaction of poor and marginalized people with provision of essential services.

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

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<sup>127</sup> <https://www.usaid.gov/what-we-do/global-health/health-systems/usaid-vision-health-systems-strengthening>

## Integration with Other Health Programs

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

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

In addition, it is expected that many systems strengthening efforts, particularly those focused on health financing, leadership and governance, and work force 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. Integrated activities should also be in line with PMI’s basic principles.

In proposing integrated activities, PMI should ensure that:

- Funding sources other than just PMI are contributing to the proposed integrated activity and describe these sources within the MOP
- For activities carried out by implementing partners with a mandate that extends beyond malaria:
  - That the implementing partners for these integrated activities have one or more staff members with expertise planning and implementing the malaria control interventions for which they are responsible



- Malaria-specific objectives and targets are included in the M&E plan for the activity and within the partner’s overall project scope of work and annual work plans
- Partners are able to account for PMI funding and measure and report on PMI objectives and targets separately from other non-malaria activities
- PMI staff review and concur with annual work plans and participate in monitoring for these mechanisms
- For activities carried out by staff or implementing partners of USG Agency other than USAID, PMI must identify an activity manager to provide oversight to the PMI funded and non-PMI funded aspects of the integrated activity to ensure maximum benefit to malaria and to ensure coordination across PMI’s overall investment.

## Promotion of Partnerships to Advance Malaria Control

Achieving PMI goals at the country-level can best be served by close partnerships with civil society organizations, including non-governmental organizations (NGOs), community-based organizations (CBOs), and faith-based organizations (FBOs), and private and public sector entities, including academic institutions. Non-governmental organizations have significantly contributed to PMI’s successes to date and it is expected that they will continue to be strong partners in PMI efforts in the future.

## Peace Corps

### *Background*

With over 3,400 total Peace Corps Volunteers (PCVs) in Africa, and over 2,400 PCVs in PMI countries in Africa across sectors (health, education Ag, etc.), the Peace Corps (PC) is well positioned to assist in the collective efforts of the USG to reduce the burden of malaria in sub-Saharan Africa. The Peace Corps labels their overall malaria program efforts across all of their endemic countries in Africa as their *Stomping Out Malaria in Africa Initiative* – in short, referred to as STOMP. In 2011, PMI teamed up with PC to harness its reach and capacity in the fight against malaria in countries in sub-Saharan African where PMI and PC have a common presence. Funding for this is provided via a USAID Small Project Assistance (SPA) program, which supplements the Peace Corps’ own appropriations.

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

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

1. **Funding PC MVs:** PMI country teams planning to support 1-3 PC MVs should budget approximately \$10,000 per malaria volunteer per year. There are two potential mechanisms to support PC MVs: (a) the USAID-Peace Corps Interagency Agreement (SPA Agreement) managed by USAID/Washington, or (b) through a bilateral PMI implementing partner (appropriate when the PC MV's scope of work involves secondment to the implementing partner). The ~\$10,000 covers housing, operational support (e.g., laptop computer), basic work supplies, work related travel, etc. Regardless of which mechanism is selected for PC MV support, the MOP should specify this support clearly in a line item in **Table 2**.
2. **Funding PCV Malaria Community Projects and malaria training events through SPA Grants:** PMI can support PCVs malaria community projects (i.e. malaria prevention mural on market wall, or school based malaria messages) through a small grants process, budgeting maximum \$10,000 per year (assuming previous year's small grants pipeline has been spent down). Additionally, PMI can support training events of PCVs and their counterparts, however not just training events of PCVs alone. The counterparts involved in the training events must be direct malaria/health service providers (i.e. nurse at a clinic, community health worker, district health worker, etc.) or be linked directly to an NMCP intervention strategy such as school teachers involved in malaria SBC messaging or school based net distribution campaigns. Such trainings must be coordinated with and endorsed by the NMCP. PMI support to PC training events should also be budgeted at maximum \$10,000 per year.

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

with PCVs on a community project with the funding flowing through a PMI implementing partner to ensure the right technical expertise is available and the work is coordinated closely with PMI's overall program in country.

### *Additional information – PC Malaria Volunteers*

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

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

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

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

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

PMI's country level collaboration with PCVs must be aimed at building local capacity of host country counterparts. Peace Corps Volunteer presence in communities can extend the reach of

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

### *Training/country orientation*

Peace Corps historically conducted a comprehensive ten-day Malaria “Boot Camp” training in Senegal, funded by PC (not PMI), that provide MVs – those supported by PMI and those supported by PC directly - with a basic understanding of malaria disease, key program interventions, and how MVs/PCVs can support national strategies at a grassroots level. As of January 2018, Peace Corps transitioned to a new model, which prioritizes in country trainings as well as virtual, online trainings. This country-focused model will facilitate capacity building of PCVs together with host country counterparts, while also allowing for more participation by in country malaria experts. The PMI in-country team is encouraged to collaborate with the NMCP and partners to coordinate and participate in these country-specific training for new PC MVs and their counterparts, as well as to assist with more in-depth orientation of PC MVs (i.e., sharing the NMCP Strategy, current status of malaria control nationally and sub-nationally, key country challenges, and priority activities).

### *Supervision, communication, and assessment*

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

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

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

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

Please contact Allison Belemvire ([abelemvire@usaid.gov](mailto:abelemvire@usaid.gov)), Susan Henderson ([shenderson@usaid.gov](mailto:shenderson@usaid.gov)), or Leah Moriarty ([wvp4@cdc.gov](mailto:wvp4@cdc.gov)) or for these materials, or any questions related to collaboration with Peace Corps.

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

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

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

Direct government-to-government support to NMCPs and local government entities must be in accordance with USAID regulations and procurement guidelines regarding grants to governments. Where used, direct grants to the Ministry of Health, NMCPs, or other local government entities may include support for financial management and tracking of the funds provided. Technical assistance and support to Ministry of Health, NMCPs, or other local

government entities to build their capacity can be part of the scope of work requested of PMI implementing partners, and should be described in MOP budget activity lines.

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

## **Field Epidemiology Training Program**

PMI supports efforts to initiate and strengthen local epidemiologic and laboratory data collection, management, analysis, and dissemination capacity in PMI-supported countries. As one approach to strengthening the long-term capacity of this health system component, country teams may consider supporting training through the CDC FETP national level training efforts. In 2016, CDC reconfigured their FETP program to a three-tiered pyramid model consisting of frontline (short-term 3 month training), intermediate (9-12 months of training), and advanced two-year training. PMI support can be directed to the advanced program, which consists of a two-year, full-time training program that helps MOHs build sustainable capacity for local detection and response to health threats, including sudden increases in malaria transmission. The aim is that over time, PMI investments in FETP will produce a cadre of public health workers that use science and data to identify, respond to, and manage acute health problems with appropriate strategies and policies and that this cadre will have positive impacts of malaria program efforts following completion of training.

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

Approximately 20-25% of the FELTP advanced training program time is spent in classroom instruction and 75% on field assignments, often including malaria control activities. The training

is competency-based with close supervision, didactic and inductive teaching which includes courses in epidemiology, communications, economics, and management. Trainees also learn quantitative and behavioral-based strategies for mitigating public health problems. The trainees provide epidemiologic services to the Ministry of Health during their training, including surveillance system assessments and outbreak investigations, and gain experience in reporting their findings and recommendations to high-level decision makers, stakeholders, and the media. Graduates receive a certificate or, in some advanced programs, a Master of Public Health degree.

FETPs are helping to realize the long-term health systems capacity development component of the USG's Global Health Security Agenda to which PMI aims to contribute. As of FY 2018 planning, PMI is supporting FETP advanced program trainees in twelve countries: Angola, Burma, Cameroon DRC, Ethiopia, Ghana, Kenya, Mozambique, Nigeria, Rwanda, Tanzania, and Uganda.

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

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

Although levels of financial support for malaria-focused FETP residents and the costs of training will vary by country, PMI has established budget guidance parameters for PMI support for FETP. PMI support for FETP trainees is external to salary provided by the Ministry of Health. PMI support contributes to the CDC program that includes two years of training per trainee and includes tuition towards a certificate or degree (if applicable), a modest training stipend, field site supplies, as well as travel expenses for didactic courses, field investigations, supervision, and

scientific conferences. PMI funding for FETP cannot be used to support salaries of FETP RAs or salaries of any FETP residents or any other staff associated with the FETP program. PMI country teams proposing support for FETP trainees should budget between \$80,000 to a maximum of \$150,000 per trainee per two-year assignment (\$40,000 to \$75,000 per resident annually) to support the FETP program in their FY 2019 MOP budgets (please use country specific cost estimates when available without exceeding the maximum threshold allowed). No more than \$300,000 per year and four trainees at a time can be supported (two trainees in the new/starting cohort and two trainees in their second and final year of the advanced FETP training program). PMI country teams need to ensure that PMI funding is not displacing CDC appropriated, Global Health Security, or other USG funding supporting FETP program activities in country. PMI country teams can explore requesting a PMI implementing partner with district level implementation focus to include support for training district level health officers through the CDC FETP frontline program in their annual work plan where CDC FETP frontline programs exist. Country teams should be careful to ensure that the training does not duplicate ongoing PMI supported training and capacity building efforts. If country teams choose to prioritize support for this training within a PMI partner's work plan, the PMI team should consult the in country FETP program for exact costs but it is expected that the implementing partner will need to budget no more than \$10,000 per student. Where PMI country team's prioritize support of trainees participating in a frontline/short-course FETP program will not be through AFENET, but through a PMI implementing partner. The majority of PMI implementing partners work at subnational levels and would be able to provide the necessary support needed for a successful partnership with the FETP Frontline programs.

PMI country teams should ensure appropriate indicators are in place to document the impact of PMI support for the FETP. PMI's decision to support FETP in the early days of PMI was taken with the expectation that graduates employment following graduation would be tracked in order for PMI to evaluate the extent to which FETP is building cadres of staff that remain within the MOH, to document how PMI investments in this program continuing to have lasting impact. Countries are expected to annually update a PMI-FETP progress tracking spreadsheet which is sent to the countries for completion and then to USAID Washington per CDC IAA reporting requirements. The following indicators will be tracked:

- total number of FETP trainees enrolled and specifically, number of malaria FETP trainees enrolled
- total number of FETP trainees graduated
- total number of FETP trainees who are employed by the NMCP or other malaria programs after graduation (title and position) (PMI in country teams are to maintain a list of graduates and track annually their continued employment with the MOH)
- list of malaria projects completed with some details about the activity or response effort if a malaria outbreak investigation



- list of products (reports, publications and presentations) from malaria-related projects that were disseminated beyond the FETP program
- list of any malaria training conducted for FETP trainees
- success stories

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# SOCIAL AND BEHAVIOR CHANGE

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

**Term Change:** Many development and public health entities, including USAID, have adopted the term social and behavior change (SBC) to encompass the factors beyond communication that influence human behavior. To better align PMI's efforts with the field and in recognition of the diverse range of interventions employed in behavior change efforts, PMI has shifted terminology from Social and Behavior Change Communications (SBCC) to SBC.

**Malaria Behavior Survey:** The Malaria Behavior Survey (MBS) is a cross-sectional household survey designed to measure malaria-related behaviors and the internal and social factors associated with those behaviors using a theory-driven and standardized methodology. To facilitate strong, data-driven, theory-informed SBC interventions, the SBC Technical Team recommends countries conduct an MBS a minimum of every five years.

**Narrowing of Focus Behaviors:** To ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, the SBC Technical Team recommends that country teams narrow the focus of SBC efforts in the countries they support. Country teams should identify no more than 2-3 specific malaria behaviors to focus their efforts around. That focus should be further refined by geography and target population and should support the National Malaria SBC Strategy and National Malaria Strategic Plan.

**Coordination and Collaboration with Service Delivery:** A growing area of focus for PMI's SBC efforts is coordination with service delivery. The SBC Technical Team recommends that country teams ensure there is close collaboration between service delivery and SBC actors. Collaboration should include regular coordination meetings, message harmonization, information sharing, monitoring, and the development of joint strategies as appropriate.

**IRS and SMC:** Acceptance and uptake of IRS and SMC are distinct from many other malaria-related behaviors. They do not require maintenance of a specific behavior over an extended period of time and, in many instances, vector control or service delivery partners lead community mobilization efforts. The SBC Technical Team encourages country teams to work with their SBC partners to focus their efforts on other malaria prevention and control behaviors, leaving the community mobilization elements inherently tied to IRS and SMC to their respective implementing partners.

## Introduction

Achieving and maintaining PMI and National Malaria Control Program (NMCP) goals depends on the acceptance and correct and consistent use of proven interventions (e.g., ITNs, IRS, RDTs, ACTs, IPTp, and SMC). When tailored to specific country contexts and needs, social and behavior change (SBC) activities play a critical role in promoting uptake of these interventions and achieving the desired individual-level and public health impact. Thus, to improve the overall quality of malaria control efforts that contribute to reductions in malaria morbidity and mortality, PMI supports a range of SBC activities to increase uptake and correct and consistent use of malaria interventions.

## Key Areas of PMI Support for SBC

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

### *Capacity Strengthening*

To ensure sufficient host country capacity for malaria SBC activities, PMI supports capacity strengthening efforts related to the design, implementation, monitoring, and evaluation of SBC activities. Capacity strengthening activities should be aimed at National Malaria Control Program (NMCP) staff, especially those directly involved with SBC activities, and may include Ministry of Health staff, such as those from a country's Department of Health Promotion.

#### *National and sub-national capacity strengthening activities*

At the national and sub-national level, PMI supports the following SBC capacity strengthening activities:

- **Global and Regional Coordination and Collaboration:** Global and regional coordination and collaboration play an important role in ensuring high-quality malaria SBC activities. Participation in regional and global efforts allows for the exchange of ideas and best practices, as well as the sharing of tools and resources. PMI supports such activities and, when appropriate, facilitates and encourages the participation of NMCP and Ministry of Health staff in regional meetings and technical organizations such as the [RBM Social and Behavior Change Communication Working Group](#) (RBM SBCC Working Group).<sup>128</sup> PMI also strongly encourages engagement in online collaboration and coordination fora, such as the [Springboard for Health Communication Professionals](#).<sup>129</sup>

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<sup>128</sup> The RBM SBCC Working Group was formerly known as the RBM Communication Community of Practice. Additional information is [available online](#) and from the PMI SBC Technical Team.

<sup>129</sup> <https://springboardforsbc.org/>

- **Malaria SBC Technical Working Group:** Given the cross-cutting nature of SBC, a malaria SBC coordinating committee or technical working group is critical. Such a group facilitates information sharing and strengthens an NMCP's ability to coordinate SBC design, implementation, and monitoring and evaluation across and within ministries, donors, and non-governmental and private sector partners. PMI supports the establishment and ongoing maintenance of such a group, which should be convened regularly to share information and facilitate planning across various technical areas and partners.
- **Training and Development:** A critical component of the successful design, implementation, and monitoring and evaluation of SBC programs is ensuring there is sufficient trained and experienced staff to support such activities. For that reason, PMI supports the participation of NMCP and Ministry of Health staff in training and development activities related to malaria SBC. A number of training options exist, including local and virtual options, and can be found in the appendix of this chapter.
- **Technical Assistance:** PMI also supports targeted technical assistance (e.g., training, mentoring) to NMCPs and other relevant ministries. Technical assistance is typically focused on planning and development of SBC activities and resources, including the selection of appropriate indicators for monitoring and evaluation and review of existing data to inform SBC strategies and interventions.

### *Development of national malaria SBC strategy*

PMI supports the development or revision of a National Malaria SBC Strategy within a country's broader National Malaria Control Strategy. Such strategies are critically important as they guide donors' and implementing partners' SBC activities and help to ensure a deliberate and harmonized approach to malaria SBC in a given country. PMI should work with the NMCP to ensure the National Malaria SBC Strategy is clearly linked to national malaria control objectives and is routinely used to guide implementation of malaria SBC activities. Furthermore, the National Malaria SBC Strategy should reflect global best practices, including those outlined in the [RBM Partnership to End Malaria's Strategic Framework for Malaria Social and Behaviour Change Communication 2018-2030](#).<sup>130</sup> A [How to Develop a Communication Strategy Guide](#)<sup>131</sup> and [examples of National Malaria SBC Strategies](#)<sup>132</sup> can be found on the Health Compass. Technical assistance is also available from USAID and should be utilized if there is not sufficient capacity in country to support the development or revision of a National Malaria SBC Strategy.

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<sup>130</sup> <https://endmalaria.org/sites/default/files/RBMSBCCFramework2018-2030English.pdf>

<sup>131</sup> <https://www.thecompassforsbc.org/how-to-guides/how-develop-communication-strategy>

<sup>132</sup> <https://www.thecompassforsbc.org/trending-topics/malaria-sbcc-strategies>

## *Design and Implementation*

At the core of PMI's approach to SBC is the use of data to design and implement high-quality, targeted interventions that reflect a comprehensive understanding of the multitude of factors that support or inhibit the practice of desired malaria prevention and control behaviors. This includes social (gender norms, social support, etc.), internal (attitudes, self-efficacy, etc.), and environmental factors (economic barriers, accessibility of services, etc.), and resulting interventions can be communication or non-communication-based.

Primary behaviors of interest include correct and consistent net use; early and frequent ANC attendance; prompt careseeking for fever; and adherence to national guidelines for health workers. However, to ensure the most strategic allocation of resources and the deployment of high quality, targeted SBC interventions, country teams must make decisions about the desired focus of SBC efforts in the countries they support. To make such decisions, country teams, with support from the SBC Technical Team and in collaboration with appropriate working groups in country, should regularly assess what is known about the practice of key malaria behaviors (such as the ratio of ITN use given access), with what is known about the internal, social, and environmental factors that influence the practice of those behaviors (such as the fact that self-efficacy is associated with increased ITN use).

By triangulating actual behavior with data on behavioral determinants and demographic information, country teams can make strategic decisions about the appropriate behavioral focus of their activities. The SBC Technical Team recommends that country teams identify no more than 2-3 specific malaria behaviors to focus efforts around. This includes both community member and health worker behaviors. This focus should be further refined by geography (e.g., specific districts, zones, or provinces) and target population (e.g., health care providers, adolescent mothers, male heads of households, etc.), and should support the National Malaria SBC Strategy and National Malaria Strategic Plan.<sup>133</sup> Data sources for such an exercise can be quite varied and are outlined in more detail in the section on monitoring and evaluation.

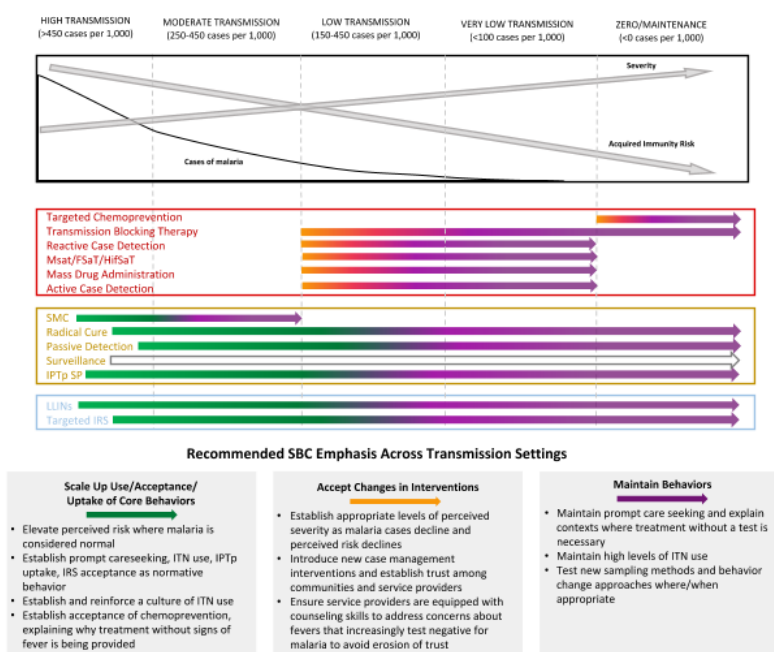
When deciding which behaviors to prioritize, country teams should carefully consider the gains that are likely to be achieved through an SBC intervention. For instance, when reviewing the internal, social, and environmental factors influencing the uptake of a specific behavior, it may become clear that the most important factor influencing the behavior is related to access and a behaviorally focused intervention would be unable to successfully address that factor. Using a simple example, an SBC activity to increase patient demand for IPTp will have limited success if SP stockouts are widespread. Conversely, a situation where SP is available at ANC clinics, but

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<sup>133</sup> It is likely that the National Malaria SBC Strategy will have a broad behavioral focus and encompass all desired malaria control and prevention behaviors. However, to best focus PMI resources, PMI-supported activities should, to the extent possible, focus on a narrower subset of behaviors as identified through in-country discussions and the assessment process described above.

where there is a common belief among ANC providers that IPTp is ineffective, would indeed call for a well-designed SBC activity targeted to service providers. Similarly, this prioritization effort could reveal that uptake of certain desired behaviors is already quite high in a given country or region. In such an instance, especially if uptake of other behaviors is low, it might not make sense to focus PMI SBC resources on trying to achieve small gains for a behavior that is otherwise widely adopted. Country teams are also encouraged to consider where their country falls on the transmission continuum and the implications for the appropriate behavioral focus for their country. The figure below provides an overview of such considerations, which are described in more detail in the Health Communication Capacity Collaborative’s (HC3’s) report titled [SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low, and Zero Malaria Transmission](#).<sup>134</sup>

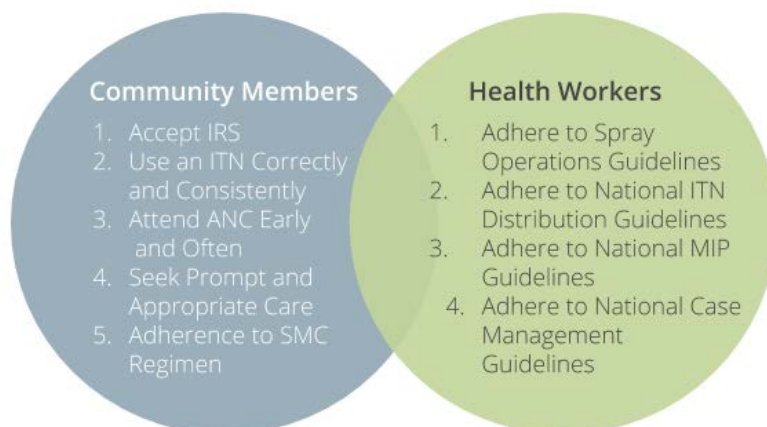
**Figure 1. Malaria Transmission Intensity and SBC Focus**



To assist country teams with discussions about the appropriate behavioral focus for their PMI SBC investments, the table below lists common behaviors associated with PMI-supported interventions. The behaviors are divided based on whether the emphasis is placed on the behavior of community members or health workers. Please note, however, the list is only intended to serve as a starting point for discussions about the behavioral focus of PMI’s SBC investments. Ultimately, through a careful assessment of new and existing data and conversations with implementing partners and host country counterparts, country teams should identify 2-3 specific behaviors, as well as corresponding target geographic areas and populations, to focus PMI’s SBC investments for a given period.

<sup>134</sup> <http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf>

**Figure 2. Common Focus Behaviors Associated with PMI-Supported Interventions**



Once specific behaviors, geographic areas, and target populations are identified, country teams, in collaboration with implementing partners and host country counterparts should begin the process of designing SBC interventions that are responsive to the behavioral determinants identified through the assessment process.

Drawing on best practices, as well as a [comprehensive evidence review conducted by Breakthrough Action](#),<sup>135</sup> PMI identified six essential components of malaria SBC activities:

- Formative assessments on barriers and facilitators;
- A theory-informed, strategic conceptual model;
- Audience profiles and segmentation into homogenous subgroups;
- Tailored interventions that utilize a mix of communication channels;
- Actionable, audience-specific, pre-tested messages; and
- Well-timed, programmatically useful monitoring and evaluation.

These components should be integrated throughout all PMI-supported SBC interventions. Country teams should review implementing partner work plans and deliverables and work with host country counterparts to ensure planned interventions thoroughly incorporate all key components. More details about each component are provided in the sub-sections that follow.

### *Formative assessments on barriers and facilitators*

Designing SBC activities requires a thorough understanding of not only the target behaviors and audiences, but also the steps needed to practice the behaviors and the context-specific factors preventing or supporting the practice of those behaviors. SBC activities that resonate with target 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

<sup>135</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

assessments to identify community-specific factors that prevent or support malaria-related behaviors. Formative assessments should also be used to inform decisions about the most strategic focus for PMI's SBC activities in a given country.

Formative assessments should involve a review of existing country-level quantitative and qualitative data on human behavior and malaria epidemiology and/or the generation of new data on desired malaria behaviors. Data sources might include information collected from national household surveys, like the 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. Two data sources that may be especially helpful for informing SBC programming and planning are described in more detail below.

- **Malaria Behavior Survey:** The Malaria Behavior Survey (MBS) was designed by HC3 and Breakthrough ACTION in collaboration with the SBC Technical Team. It 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. By providing data on the internal and social factors that influence the uptake of malaria-related behaviors and services, the MBS provides critical data to inform the design, implementation, and evaluation of SBC interventions. It can also play a key role in guiding decisions about which behaviors a country should focus its PMI-supported SBC activities around. To facilitate strong, data-driven, theory-informed SBC interventions, the SBC Technical Team recommends countries conduct an MBS a minimum of every five years. The decision to conduct an MBS, including the timing and scope, should be negotiated with the NMCP. The MBS is implemented through Breakthrough ACTION and countries should contact the SBC Technical Team for additional information on budgeting and planning for an MBS.
- **ITN Access and Use Report:** Developed by VectorWorks, the ITN use:access ratio provides data on the behavioral gap for net use by estimating the proportion of the population using nets among those that have access to an ITN within their household. The target ratio is at least 80%, while a ratio of less than 60% is considered poor and suggests there may be a need for SBC interventions aimed at increasing ITN use. Country teams should refer to the annual [ITN Access and Use Report](https://breakthroughactionandresearch.org/itn-use-and-access-report/)<sup>136</sup> produced by VectorWorks for their country-level ratio as well as ratios by region/province, wealth quintile, and urban or rural residence. The report also includes programmatic implications, which can be used by countries to help determine if consistent ITN use should be a prioritized behavior for their SBC interventions.

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<sup>136</sup> <https://breakthroughactionandresearch.org/itn-use-and-access-report/>



### *Development of a theory-informed, strategic conceptual model*

High-quality SBC activities must be based on a logical framework that identifies: the target behavior; factors preventing or supporting the behavior in the target population (why people do *or* do not engage in the behavior); behavioral and communication objectives to address these factors; specific SBC activities to be undertaken; and the expected outcomes. Use of behavioral theories is critical to the development of a strong logic model. Examples of theories include: the Health Belief Model, Stages of Change, and Social Learning Theory. These, as well as a number of other theories are described in more detail on the [National Institutes of Health's Office of Behavioral and Social Science Research e-Source](#).<sup>137</sup> It is important to remember, however, that there is no right theory to use. Behavioral theories can be adapted, modified, or combined based on the results of formative assessments and can help rationalize and communicate why certain approaches are used. The key is ensuring that a theory-informed, clear, and comprehensive logic model is used to guide SBC interventions. Health Compass' [How To Do a Logic Model](#)<sup>138</sup> provides guidance on the development of such a model.

### *Profiling and segmentation of audiences into homogenous subgroups*

Audience analysis and segmentation is a critical component of any successful SBC intervention. It provides a systematic method for incorporating context-specific factors that prevent or support desired behaviors, such as cultural practices or gender norms, into the development of activities, products, and messages. The first step in the audience analysis and segmentation process involves identification of the primary/priority audience (individuals whose behavior needs to be changed) and the secondary/influencing audiences (individuals who influence the behavior of the primary audience). Decisions about the appropriate primary and secondary audience should be informed by data collected through the formative assessment process, as well as by decisions about the appropriate focus of PMI-supported SBC interventions. Once primary and secondary audiences have been identified, detailed profiles should be developed for each. A description of the characteristics that should be included in an audience profile, as well as step-by-step description of the audience analysis process can be found on Health Compass' [How To Do An Audience Analysis](#).<sup>139</sup>

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

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<sup>137</sup> [www.esourceresearch.org/eSourceBook/SocialandBehavioralTheories](http://www.esourceresearch.org/eSourceBook/SocialandBehavioralTheories)

<sup>138</sup> [www.thecompassforsbc.org/how-to-guides/how-develop-logic-model-0](http://www.thecompassforsbc.org/how-to-guides/how-develop-logic-model-0)

<sup>139</sup> <https://www.thecompassforsbc.org/how-to-guides/how-do-audience-analysis>

different SBC messaging and/or interventions. Detailed information on audience segmentation, as well as guidelines for defining segmentation criteria, can be found on Health Compass' [How To Do Audience Segmentation](#).<sup>140</sup>

### *Tailored interventions that utilize a mix of communication channels*

There are a variety of approaches that can be used to communicate with target audiences. Broadly, these approaches include mass media, interpersonal communication (IPC), community mobilization, and information and communication technology (ICT). Drawing on the [comprehensive evidence review conducted by Breakthrough Action](#), PMI recommends a transmedia approach to SBC that uses a mix of communication channels. The evidence suggests that a multi-channel, multimedia approach is needed to achieve high levels of exposure to SBC activities and that there is a dose-response relationship between the number of sources/messages recalled and the likelihood of adoption/maintenance of malaria-related behaviors.<sup>141</sup>

Within that framework, PMI has historically recommended an approximately 70 percent/30 percent split between interpersonal communication and mass media activities. This recommendation recognizes that other donors – primarily the Global Fund – have historically focused their support on mass media and that PMI's investments should complement 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 a few key considerations related to each of the communication channels identified above and provides insight into when a given channel might be appropriate. Ultimately, however, the appropriate mix of channels should be determined by country context, including epidemiology, situation analysis, behavioral analysis, audience analysis, as well as available budget and priorities of other SBC stakeholders. Additional guidance on selecting appropriate communication channels can be found on Health Compass' [How to Develop a Channel Mix Plan](#)<sup>142</sup> and by reviewing the [Malaria SBCC Evidence Database](#).<sup>143</sup>

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<sup>140</sup> <https://www.thecompassforsbc.org/how-to-guides/how-do-audience-segmentation>

<sup>141</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

<sup>142</sup> <https://www.thecompassforsbc.org/how-to-guides/how-develop-channel-mix-plan>

<sup>143</sup> <https://healthcommcapacity.org/malaria-evidence-database/>

**Table 1 - Communication Channels**

Approach	Description	Channels
Mass Media	<ul style="list-style-type: none"> <li>Extensive reach, but one-way communication may be limiting for some behaviors</li> <li>Best for messages intended for large audiences, such as for raising awareness about goods, services, and events</li> <li>Useful for reinforcing interpersonal communication, community-based, and ICT activities</li> <li>Can help to promote supportive social norms</li> <li>Allows for dissemination to diverse and hard-to-reach audiences, depending on media access</li> </ul>	<ul style="list-style-type: none"> <li>Broadcast media (e.g., radio, television, video, serial dramas, game shows)</li> <li>Print media (e.g., magazines, newspapers, pamphlets, posters, and pamphlets)</li> <li>Outdoor media (e.g., billboards)</li> </ul>
Interpersonal Communication	<ul style="list-style-type: none"> <li>Face-to-face interaction, but costly and with limited reach</li> <li>Effective at converting knowledge to action and targeting behaviors that are more problematic or engrained and that require more sensitive communication</li> <li>Facilitates and encourages appropriate action, especially among marginalized populations, and helps people to discuss beliefs and feelings about their ability to take appropriate action;</li> <li>Useful for targeting behaviors for which multiple family members are a part of the decisionmaking process</li> <li>Reinforces mass media, community-based, and ICT activities</li> </ul>	<ul style="list-style-type: none"> <li>Home visits</li> <li>Counseling</li> <li>School demonstrations</li> <li>Peer education</li> <li>Outreach</li> <li>Hotlines</li> <li>Provider (service communication)</li> </ul>
Community Mobilization	<ul style="list-style-type: none"> <li>Participatory process that can help stimulate community dialogue and motivate collective solutions</li> <li>Allows for the leveraging of social support, which can help change social norms and increase the adoption of desired behaviors</li> <li>Reaches slightly more people than interpersonal communication, but requires time and relationship building</li> </ul>	<ul style="list-style-type: none"> <li>Community mobilization</li> <li>Community dialogue</li> <li>Community drama</li> </ul>
Information and Communication Technology	<ul style="list-style-type: none"> <li>Potential for interventions to be highly tailored and to engage younger individuals</li> <li>Able to share and adjust information quickly</li> <li>May allow users to engage in dialogue and share information, but control over messaging and content may be limited and many interventions require literacy</li> </ul>	<ul style="list-style-type: none"> <li>Mobile phone apps</li> <li>SMS</li> <li>Online platforms</li> <li>Social media</li> <li>Interactive voice response (IVR)</li> </ul>

**Creation of actionable, audience-specific, pre-tested messages**

At the core of high-quality SBC interventions is the development and testing of messages. Well-designed messages: (1) include the information that is needed to encourage behavior change, and (2) have a clear behavioral and communication objective. Behavioral objectives reflect the behavior targeted by the SBC activity, while communication objectives reflect the behavioral factors that have been identified as influencing uptake of that behavior, sometimes referred to as an intermediate outcome. For example, a behavioral objective for an SBC activity may be to increase ITN use among pregnant women, while the corresponding communication objectives may be to increase the proportion of pregnant women who feel they are at risk for malaria and that the consequences could be severe. The appropriate corresponding message would likely focus on highlighting the risks associated with malaria for pregnant women and clear steps that pregnant women can take to avoid those risks, such as the use of an ITN. Evidence suggests that the inclusion of specific actionable steps that lead to improved outcomes is also a critical component of SBC messaging.<sup>144</sup> SBC activities that emphasize specific malaria-related behaviors (particularly behaviors associated with intervention use) are most likely to achieve substantial behavior change, compared to activities only focused on raising risk perception. The Health Compass’ [How to Design SBCC Messages](https://www.thecompassforsbc.org/how-to-guides/how-design-sbcc-messages)<sup>145</sup> provides a step-by-step guide to the message development and pre-testing process.

<sup>144</sup> [http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report\\_Final.pdf](http://healthcommcapacity.org/wp-content/uploads/2018/11/Malaria-SBCC-Evidence-Report_Final.pdf)

<sup>145</sup> <https://www.thecompassforsbc.org/how-to-guides/how-design-sbcc-messages>

### *Well-timed, programmatically useful monitoring and evaluation*

There is an increasing focus across PMI to develop more comprehensive and systematic data on the impact of SBC on malaria control and prevention. With this focus comes a greater emphasis on accountability and reporting of SBC activities, including the development of comprehensive monitoring and evaluation plans, the selection of appropriate indicators, and the measurement and tracking of those indicators. Given the importance of such activities, the role of monitoring and evaluation for SBC is explored in greater detail later in this section. It should be noted here, however, that a clear plan for monitoring and evaluating SBC activities should be developed at the time of intervention design.

### *Coordination with Service Delivery*

A growing area of focus for PMI's SBC efforts is coordination with service delivery. Coordination between SBC and service delivery actors aligns supply- and demand-side efforts and can provide critical data for monitoring the success of behavior change interventions. For instance, by sharing monitoring data across SBC and service delivery mechanisms, partners can gather important information that they might not otherwise have access to. This, in turn, makes it possible for SBC programs to use service statistics to understand if their demand creation efforts are producing an effect, and allows service delivery partners to glean useful insights on provider and client beliefs, misconceptions, and norms. To that end, the SBC Technical Team recommends that country teams ensure there is close collaboration between all service delivery and SBC actors. Collaboration should include regular coordination meetings, message harmonization, information sharing, monitoring, and the development of joint strategies as needed.

Coordination with service delivery is also critical because facility- and community-based service providers play a key role in malaria control and prevention as the primary conduit between service delivery points and patients. From an SBC perspective, providers are both a channel for communication targeted to patients (service communication) and a target audience for SBC activities (provider behavior change). These concepts are explored in more detail below.

### *Service communication*

Service communication is the use of SBC activities by healthcare providers to influence service-related behaviors among patients across the continuum of care at both facility- and community-based delivery points—before, during and after services. Effective service communication can help improve provider-patient interactions, increase the adoption and maintenance of healthy malaria-related behaviors, and contribute to creating a cycle of good provider/patient relations and increased demand for, and use of, malaria control services. A helpful resource for

developing SBC activities for health services is the [Service Communication Implementation Kit](#).<sup>146</sup>

Both service delivery and SBC actors play a role in service communication. Service delivery partners may need to play a role in the implementation of SBC activities centered around improving service communication at the community or at facility level. As such, and as noted above, 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 is addressed.

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

Unlike service communication, which focuses on using providers as a communication channel, provider-behavior change efforts focus on providers as an audience for SBC interventions. There is widespread recognition that provider behavior plays a critical role in the quality and type of care patients receive. Provider-behavior change activities seek to positively influence provider behavior by addressing internal factors, such as personal attitudes and beliefs, social norms, personal and community values, status and recognition, that influence provider behavior. However, at present, limited data is available around provider behaviors. Formative assessments will likely be needed to design SBC activities that effectively address the internal factors that influence provider behaviors and should be done in collaboration with service delivery partners who have valuable information on provider behaviors. A helpful resource for designing provider-behavior change activities is the [Provider Behavior Change Implementation Kit](#).<sup>147</sup>

### ***Monitoring and Evaluation***

There is increasing focus across PMI on the use of comprehensive and systematic data to make strategic programming decisions. As part of this effort, there is a need for more regular 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, including the selection of appropriate indicators, the measurement and tracking of those indicators, and the integration of 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

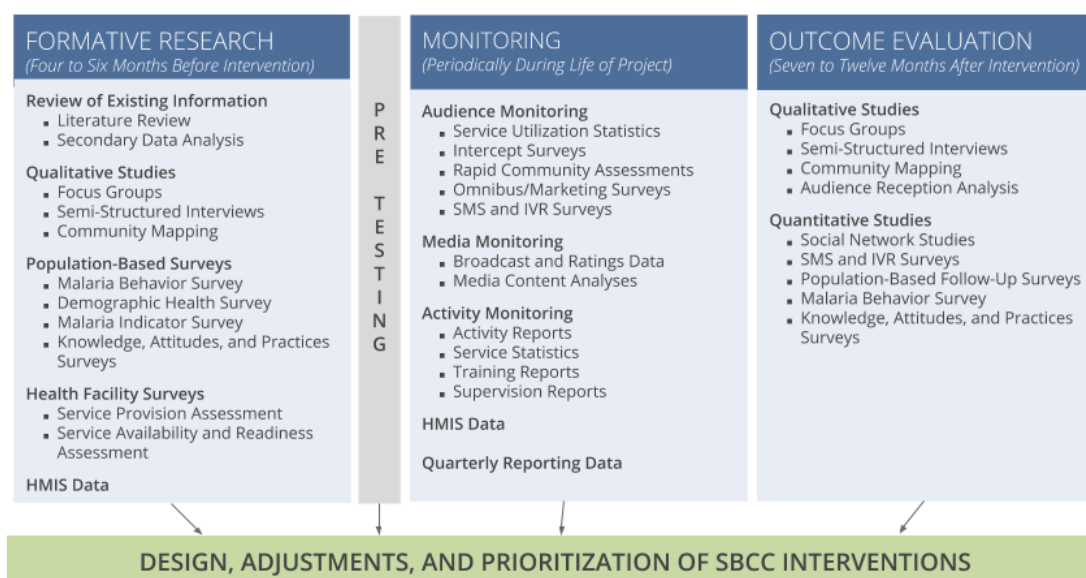
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<sup>146</sup> <http://sbccimplementationkits.org/service-communication/>

<sup>147</sup> <https://sbccimplementationkits.org/provider-behavior-change/>

achieved through the development of a comprehensive and systematic monitoring and evaluation plan that draws on the previously identified logic model and behavioral and communication objectives for the selected SBC approach. Monitoring and evaluation plans should use a practical framework (see Figure 2) to illustrate activities for formative assessments; baseline evaluation and indicator development; process and audience monitoring; and endline (outcome) evaluation.

**Figure 3. Framework for SBC Monitoring and Evaluation**



Partner monitoring and evaluation plans for SBC activities should include the following components:

- Behavioral objectives, communication objectives, and a detailed description of the SBC activities designed to address those objectives;
- Indicators for each objective, including operational definitions;
- Targets for both the desired behavioral outcomes and the associated behavioral factors;
- A timeline for data collection and analysis in relation to activity implementation (i.e., formative, baseline, midpoint, endline); and
- Information about the data sources that will be used to calculate the indicators, the reporting frequency, and responsible parties.

More details about each of these components, as well as guidance on developing a comprehensive and systematic monitoring and evaluation can be found in the RBM Partnership to End Malaria’s guidance titled [Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide](#).

### Data sources for monitoring and evaluation activities

Monitoring and evaluation data may be captured using 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), and other relevant sources.

- **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, careseeking, and testing and treatment. However, 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. It can also be costly and time consuming to negotiate the addition of malaria SBC questions into such surveys. KAP studies generally offer a more flexible alternative, however, there are no standard modules for such studies and thus they require expertise in questionnaire design, sampling, implementation, and analysis. Furthermore, KAP studies often do not collect systematic data on the full range of ideational variables that influence the uptake of malaria-related behaviors. The MBS, on the other hand, is designed to collect systematic data on the full range of ideational variables and should be integrated into monitoring and evaluation plans whenever possible and appropriate.
- **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. Existing health facility data sources, such as routine data (e.g., HMIS) and commodity inventories, also provide insight on service 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:** Activity reports from implementing partners can be used as data sources for monitoring and evaluation of SBC activities. Other monitoring tools, such as media monitoring, mobile phone surveys, media content analysis, and rapid exit surveys, can also be useful in a monitoring and evaluation plan for an SBC activity. 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 tool that can be used. Omnibus surveys can be used to track exposure/recall and assess changes in targeted behavioral factors. National or regional-level samples can be obtained but sampling strategies are not as robust as DHS

and MIS surveys. For more details on the advantages and limitations of all data sources mentioned, please refer to [RBM Partnership to End Malaria's SBCC Indicator Reference Guide](#)<sup>148</sup> and [Breakthrough ACTION's SBC Monitoring Guidance](#).<sup>149</sup>

### **Formative assessments**

Formative assessments should be conducted prior to the design of SBC interventions. Formative assessments 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 the MBS, may be needed to fill gaps. After data has been gathered from a variety of sources, epidemiological data, data on behavioral determinants, and data on actual behavior should be triangulated to help inform the development of a strategy that clearly identifies priority malaria control and prevention behaviors; key behavioral determinants associated with those behaviors, and the most appropriate approaches to reach the intended audience.

### **Baseline evaluation and indicator development**

Baseline evaluations should be conducted following formative assessments to measure conditions before implementation. Some baseline data may already be available from formative assessment activities. However, during this phase, the development of indicators that can be used to monitor and evaluate the results of SBC interventions is critical. The selection of indicators for evaluation at baseline and endline should be based on an activity's behavioral and communication objectives and should include indicators that measure actual behavior, as well as those that measure behavioral determinants (e.g., knowledge, attitudes, self-efficacy, response efficacy, perceived risk, severity and norms). As appropriate, indicators for both beneficiaries and providers should be considered. For more information on indicator development and prioritization, please refer to the [RBM Partnership to End Malaria's SBCC Indicator Reference Guide](#), which was developed to ensure a rigorous standardized approach to SBC monitoring and evaluation efforts. The indicators included in the reference guide are not considered required reporting indicators for PMI. However, PMI partners are strongly encouraged to use the indicators to design, monitor, and evaluate SBC activities.

### **Process monitoring and audience monitoring**

Since endline evaluations only occur periodically (often only every 2-5 years), process and audience monitoring are essential for tracking whether activities are being implemented as planned and determining if desired changes are starting to emerge in the target population (e.g., changes in knowledge, attitudes, risk, efficacy, norms). This type of monitoring can and should

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<sup>148</sup> <http://breakthroughactionandresearch.org/wp-content/uploads/2018/03/Malaria-SBCC-Indicator-Reference-Guide-ENG-2017-Sept.pdf>

<sup>149</sup> <https://breakthroughactionandresearch.org/resources/social-and-behavior-change-monitoring-guidance/>



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.

### ***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 decisionmaking. 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.

## **Special Considerations**

### ***IRS and SMC***

Acceptance and uptake of IRS and SMC are distinct from many other malaria-related behaviors. They do not require maintenance of a specific behavior over an extended period of time. Rather, they rely on acceptance and uptake of an intervention at a specific point in time in a limited geographic area. The discrete nature of these activities means that large-scale, ongoing SBC interventions are often not needed or appropriate. Rather, targeted community mobilization efforts are often better positioned to address acceptance and uptake of IRS and SMC. In many instances, vector control or service delivery partners lead community mobilization efforts for IRS and SMC. The SBC Technical Team supports this approach and encourages country teams to work with their SBC partners to focus the bulk of their efforts on other malaria prevention and control behaviors. SBC partners should, however, be positioned to collaborate with vector control and service delivery partners and provide focused technical assistance on IRS and SMC when specific questions or challenges arise.

### ***Changes in Transmission Settings***

As more and more countries move towards malaria elimination nationally and sub-nationally, the focus of SBC activities will need to shift. With declines in transmission intensity, countries will experience fewer and fewer cases of malaria and perceived risk is likely to decrease. Decreased natural immunity will, however, make imported cases more severe. In this context, SBC interventions will need to be adjusted to target different populations and behavioral factors, utilize new channels, and adjust how behavior change is measured. 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 key aspects of behavior change be considered as countries advance toward elimination. 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 SBCC for Malaria in Pregnancy: Strategy Development Guidance](#).<sup>150</sup>

### *Operational Research*

Formative assessments to further understand a behavior and the factors preventing or supporting that behavior in the absence of existing data are not operational research and are expected. That being said, as PMI country teams confront SBC-related operational research questions, those questions should be discussed with relevant stakeholders for consideration of how to prioritize and address those questions. Country teams should also consider the RBM Partnership to End Malaria's [Priority Research Areas and Approaches for Malaria SBC Programs](#), which outlines research areas and approaches that need to be explored as malaria interventions scale-up. Ultimately, as with other PMI-supported operational research activities, protocols need to be developed through the process outlined in the **Operational Research** Chapter.

### *Peace Corps*

Guidance for collaboration with Peace Corps is available in the **Health Systems Strengthening** chapter. However, as it relates to SBC activities, Peace Corps and Peace Corps Volunteers are potentially a great resource. It is recommended that PMI country teams ensure that Peace Corps' malaria SBC activities are aligned with NMCP SBC efforts, complement PMI-supported SBC activities, are evidence-based and theory-informed, and contribute to the behavioral and communication objectives outlined in the national malaria SBC strategy. Whenever possible, Peace Corps and Peace Corps Volunteers should participate in existing or ongoing SBC activities rather than designing and implementing parallel or duplicative 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.

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<sup>150</sup> <http://healthcommcapacity.org/wp-content/uploads/2018/01/HC3-Malaria-Elimination-Landscape.pdf>

- For countries that buy-in to 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 activity. 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. To ensure this occurs, PMI country teams are expected to help create strong linkages between SBC projects and other projects within the PMI portfolio. For example, SBC projects working to increase care- and treatment-seeking should be linked with service delivery projects working to improve the quality of community- and facility-based malaria case management. These linkages are especially critical given the cross-cutting and supportive nature of SBC.
- PMI country teams are also expected to coordinate SBC activities with the Global Fund Principal Recipient and other implementing partners and donors to ensure the implementation of complementary and reinforcing SBC activities.

The SBC Technical Team at PMI/Headquarters is committed to supporting PMI country teams with design, implementation, monitoring, and evaluation of SBC projects and activities. Members of the SBC Technical Team can provide virtual, as well as in person support. Virtually, SBC Technical Team members can provide support to countries by reviewing work plans, strategy documents, or other deliverables, while, through a TDY, members of the team can provide project- or intervention-level operational support. They can also contribute to the design and assessment of countries' malaria SBC mechanism(s).

Each member of the SBC Technical Team is responsible for supporting specific countries on issues related to SBC.<sup>151</sup> Similarly, to facilitate communication with PMI/Headquarters, country teams are asked to identify a single SBC point of contact. The SBC point of contact (POC) will be the primary contact for the SBC Technical Team regarding SBC in-country. The SBC Technical Team at PMI/Headquarters will send periodic updates to the field-based SBC POCs and host periodic coordination calls with the field-based SBC POCs. The SBC Technical Team also encourages SBC POCs to reach out to their SBC backstop to request assistance related to SBC activities and to share SBC work plans and deliverables.

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<sup>151</sup> For the name of the SBC backstop for your country, please contact any member of the SBC Technical Team at PMI/Headquarters.

## SBC Appendix 1 - Additional Resources

Category	Resource	Description
<b>General</b>	<a href="#">RBM Partnership to End Malaria's Strategic Framework for Malaria SBCC</a>	Framework for malaria SBC that outlines a technical and advocacy agenda for the field.
	<a href="#">Springboard for Health Communication Professionals</a>	Online platform for exchanging knowledge, experiences, and resources about SBC.
	<a href="#">Health Communication Capacity Collaborative Online Learning Center</a>	Rich repository of information on SBC, including webinars, online trainings, and toolkits.
	<a href="#">Accelerator Behaviors</a>	Tool that identifies accelerator behaviors and proposes possible program strategies.
<b>Strategy Development</b>	<a href="#">How to Develop a Communication Strategy</a>	Step-by-step instructions on how to develop a communication strategy—at any level.
	<a href="#">Repository of National Malaria SBCC Strategies</a>	Curated repository of national malaria SBCC strategies.
<b>Design and Implementation</b>	<a href="#">SBCC Implementation Kits</a>	Collection of in-depth implementation guides on various topics related to malaria SBC.
	<a href="#">Health Compass How to Guides</a>	Short guides that provide step-by-step instructions on how to perform core SBC tasks.
	<a href="#">SBCC Quality Assurance Tool</a>	Easy-to-use tool to assess and assure the quality of SBCC activities.
<b>Monitoring and Evaluation</b>	<a href="#">Developing Monitoring and Evaluation Plans for Malaria Social and Behavior Change Programs: Step-by-Step Guide</a>	Resource that introduces the elements of a monitoring and evaluation plan for malaria SBC programs.
	<a href="#">SBCC Indicator Reference Guide</a>	A streamlined, standardized set of priority indicators for malaria SBC activities.
	<a href="#">SBC Monitoring Guidance</a>	Technical notes on monitoring methods that may be used for SBC programs.

	<a href="#">Malaria SBCC Evidence Database</a>	Searchable database of literature documenting the impact of malaria SBC.
	<a href="#">Priority Research Areas and Approaches for Malaria SBC Programs</a>	Report outlining priority research areas and approaches that need to be explored and utilized as malaria interventions scale up.
	<a href="#">Checklist for Reporting on Malaria SBC Program Evaluations</a>	Checklist aimed at improving the evidence base for malaria SBC by outlining standard elements for program evaluation reporting.
<b>Specific Technical Areas</b>	<a href="#">ITN Use and Access Report</a>	Provides an estimate of the proportion of the population using nets among those that have access to one within their household.
	<a href="#">SBC for Insecticide-Treated Nets</a>	Comprehensive guide on SBC activities for all types of net behaviors, including acquisition, use, and care.
	<a href="#">Monitoring And Evaluation For SBCC - Malaria Case Management</a>	How-to guide on monitoring and evaluating SBC components of malaria case management interventions.
	<a href="#">SBC Considerations for Areas Transitioning from High and Moderate to Low, Very Low and Zero Malaria Transmission</a>	Guide to scaling up and maintaining coverage of proven interventions in countries as transmission patterns change.
	<a href="#">SBCC for Malaria in Pregnancy: Strategy Development Guidance</a>	Resource on the design of interventions for malaria in pregnancy, especially those interventions that target healthcare worker.
<b>Online Trainings</b>	<a href="#">Evidence-Based Malaria Social and Behavior Change Communication</a>	Introduction to malaria SBC theory, formative assessments, implementation, and monitoring and evaluation.
	<a href="#">Health Communication for Managers</a>	Course aimed at increasing learners' understanding of the basic principles of health communication.
	<a href="#">Health Behavior Change at the Individual, Household and Community Levels</a>	Provides introduction to conceptual tools needed to analyze health-related behaviors and the context in which they occur.
	<a href="#">Introduction to Human-Centered Design</a>	Introduction to the human-centered design process, which involves creating innovative solutions to real-world challenges

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# SURVEILLANCE, MONITORING, AND EVALUATION

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

**New:** Although a single partner may not be responsible for everything that needs to be done to strengthen routine health information systems, a list of PMI-recommended activities can be used to identify gaps across partners and prioritize support for activities (Box 1).

**Nationally representative household surveys will continue to be a key surveillance, monitoring, and evaluation (SM&E) activity:**

- In medium- to high-prevalence areas, household surveys are recommended every 2-3 years
- In low-prevalence areas, household surveys are recommended every 3-5 years.
- PMI recommends that in countries where national parasite prevalence in children under 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued.

**Health management information systems (HMIS) are a key investment area for PMI.** To better document PMI support for HMIS strengthening plans, more information should be provided on the NMCP overall strategy, the level of support (region, district, facilities, and community), and the total number of areas being targeted and covered.

**Nationally-representative health facility surveys (HFS) are primarily used for program monitoring and help monitor readiness of a health facility to provide quality care.** As a general rule, HFS should not be repeated more than every 2-3 years, depending on the information required. Note that investigations conducted in health facilities in response to a specific problem would not be considered health facility surveys.

*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.*

## **Introduction**

The goal of PMI's updated strategy for 2015-2020 involves working with NMCPs and partners to accomplish the following objectives by 2020:

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

These objectives will be accomplished by emphasizing five core areas of strategic focus: (1) achieving and sustaining scale of proven interventions; (2) adapting to changing epidemiology and incorporating new tools; (3) improving countries' capacity to collect and use information; (4) mitigating risk against the current malaria control gains; and (5) building capacity and health systems.

## **PMI Surveillance, Monitoring, and Evaluation Principles**

### *Coordination and partnership*

PMI is a member of the RBM Partnership and, as such, SM&E activities should, whenever possible, be carried out in coordination with other major partners and donor agencies, including the Global Fund, World Bank, WHO, UNICEF, DFID, etc. Surveillance, monitoring, and evaluation activities should also be in line with the principle of "The Three Ones" – one national malaria control coordinating body, one national malaria control strategy, and one national malaria control SM&E plan – by supporting national SM&E strategies and encouraging NMCP leadership in SM&E. PMI should seek ways to support and strengthen MOH and NMCP capacity in SM&E by providing appropriate technical and material resources to build human and system capacity at the various operational levels throughout the national health system. Collaboration with other USG partners such as PEPFAR, USAID MCH programs etc., should be sought.

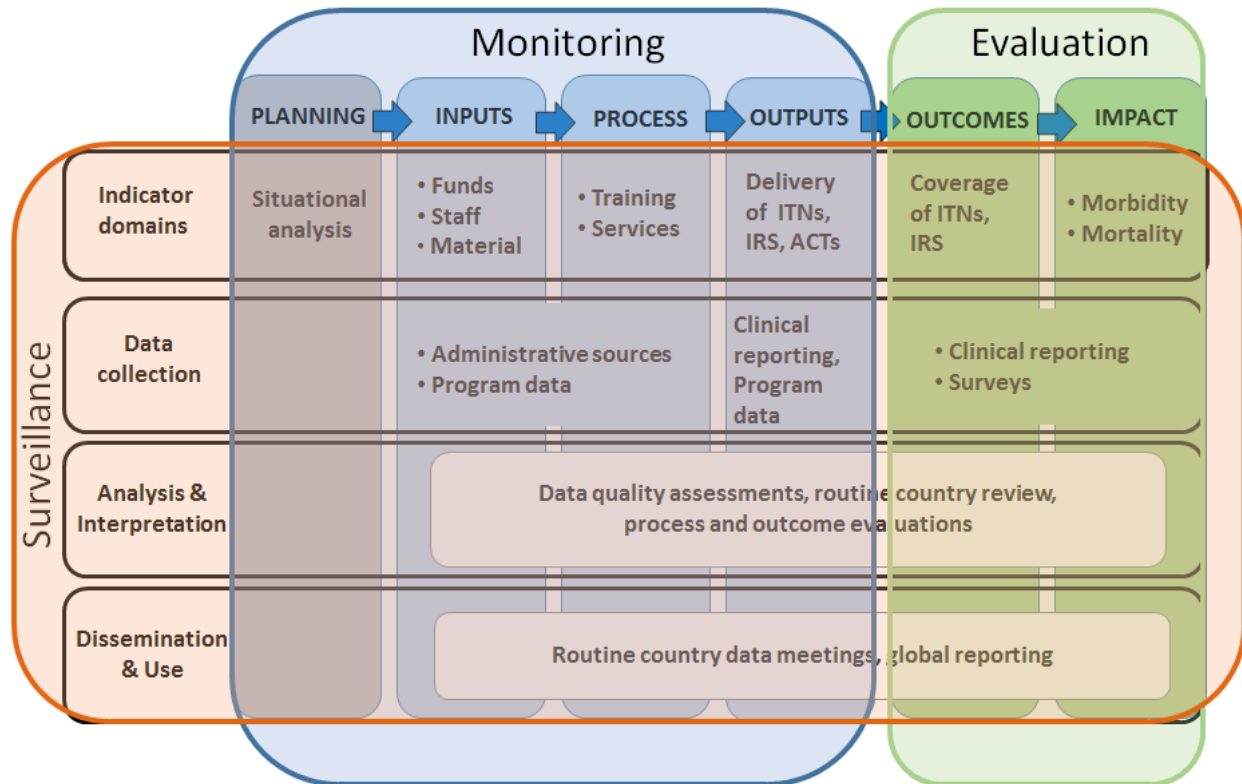
### *Cost-effective, sustainable solutions*

The PMI Headquarters SM&E Team is cognizant that funding for malaria and SM&E activities is finite and therefore strives to ensure that PMI-proposed SM&E activities are the "best buy" for countries and donors. Surveillance, monitoring, and evaluation activities should provide cost-effective long-term solutions, and promote approaches and systems that are or can become sustainable with country resources. Although efficiencies in acquiring SM&E data and information for malaria may tempt to support 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 1** 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.

Fig 1: Malaria Surveillance, Monitoring and Evaluation Framework



## Measuring PMI Objectives

Determining progress towards the three 2020 objectives requires estimating malaria morbidity and mortality in each PMI focus country. For countries nearing elimination, subnational estimates are also required. The following sections correspond with PMI's objectives and focus areas and provide a general overview of what SM&E activities are expected to be included in the MOP and supported with PMI resources.

**Objective 1- Reduce malaria mortality by one-third from 2015 levels in PMI-supported countries, achieving greater than 80% reduction from PMI's original 2000 baseline levels**



PMI has historically used DHS to track all-cause child mortality (ACCM) as an indicator of successful malaria control in high- and moderate-transmission settings. In settings with high malaria prevalence, trends in malaria mortality and ACCM are highly correlated. PMI will continue to rely on DHS as a primary source of ACCM data, and ACCM will continue to be a key indicator to assess the impact of the scale-up of malaria interventions. 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. As malaria transmission diminishes and fewer deaths are attributable to malaria, use of ACCM will become less effective as a direct indicator for tracking malaria control success (for this reason, ACCM has never been a primary indicator for malaria in the Mekong countries).

Facility-based data collected by the ministries of health and the NMCPs through routine health information systems (RHIS) are a primary data source for hospital-based deaths from malaria. It is important to emphasize that hospital-based deaths grossly underestimate the actual number of malaria deaths because many deaths occur at home, or at facilities not reporting to routine systems. However, trends in mortality can be tracked through longitudinal facility-based data collection systems and, when controlling for factors such as increasing completeness of reporting and increases in health facility use, suggest changes in malaria mortality and case-fatality rates over time.

## **Objective 2 - Reduce malaria morbidity in PMI-supported countries by 40 percent from 2015 levels**

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.

In most PMI-supported countries, RHIS data (increasingly captured via DHIS-2 platform) is the main data source for suspected and confirmed malaria cases, test positivity rates, hospital admissions, and deaths within hospitals. PMI recommends a strategy that addresses both

increased analysis of RHIS data and overall strengthening of HMIS systems, such as improving data recording and reporting, and inclusion of private and public facilities and community-level providers.

Additional guidance on these routine health information systems and population-based surveys is in the '*Guidance on SM&E Approaches and Tools*' section below.

### **Objective 3 - Assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination**

WHO previously defined the pre-elimination phase as a monthly malaria test positivity rate of less than 5% among all febrile patients throughout the year. Thus, countries approaching elimination must have a highly functioning routine health information system that includes reporting of cases diagnosed at community level. Preferred impact indicators in settings moving towards elimination would then include test positivity rate and incidence estimates based on the catchment population of the health facility.

A detailed discussion on SM&E in the elimination setting can be found in the **Elimination** chapter.

## **Five Areas of Strategic Focus**

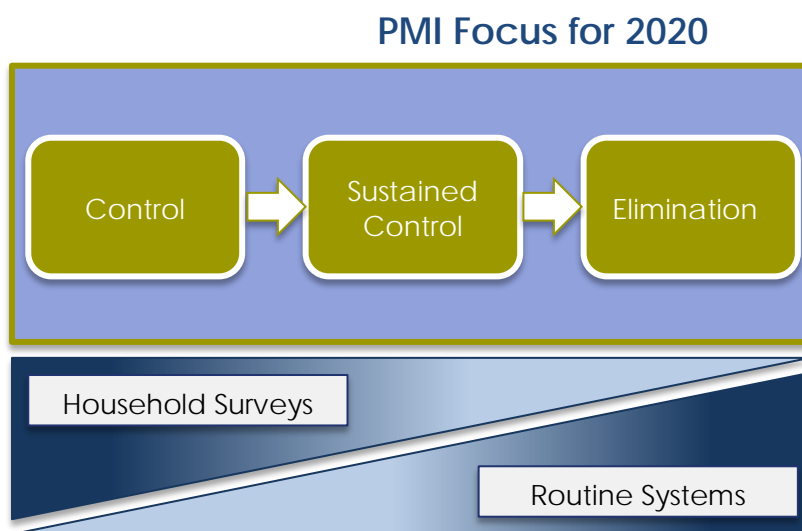
The *PMI 2015-2020 Strategy* has five areas of strategic focus that support PMI's three objectives. Focus areas need to be monitored to assess progress that will ultimately have impact on PMI's objectives. See the *SM&E Framework* (**Figure 1**) for more details on how these focus areas align with SM&E objectives.

## **SM&E for the PMI Strategy, 2015-2020**

PMI and the global malaria community have a long-term vision for the global eradication of malaria that is based on a progression through successive phases of malaria control and 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 2**). 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 2: Changing SM&E in the Context of Progressive Phases from Malaria Control to Elimination**



## Guidance on SM&E Approaches and Tools

### *Malaria disease surveillance*

Malaria disease surveillance plays an important role in the 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. Malaria surveillance data can be used to identify areas in need of more intensive interventions, and to measure the impact of interventions. When accurately recorded and reported, these data are important for monitoring changes in malaria over time. PMI recognizes that the country context – health system capacity, malaria epidemiology, implementing partner experience, among others – will determine how to best implement malaria surveillance.

For reference, the link to the WHO guidance on malaria surveillance for control areas is (<http://www.who.int/malaria/publications/atoz/9789241503341/en/>). For countries moving towards elimination, please contact the PMI Headquarters SM&E Team and Elimination Working Group for guidance. The recently updated WHO Framework for Malaria Elimination also has some useful information on SM&E activities in elimination settings (<http://www.who.int/malaria/publications/atoz/9789241511988/en/>).

### *Routine health information systems*

RHIS will be important for measuring the impact of PMI interventions going forward. The RHIS is based on clinical data passively collected from health facilities, and in some cases includes data collected from the community. The type of RHIS used by national programs will vary from country to country. The most common system used in PMI-supported countries is the HMIS.

HMIS typically include a broad set of health indicators (including several malaria indicators) representing all health services provided at the health facility. A few country programs are also using the Integrated Disease Surveillance and Response system (IDSR). IDSR typically collects and reports on a limited set of indicators on a weekly basis for a small number of epidemic-prone diseases from health facilities. Both systems are affected by health-seeking behavior. The numbers of malaria cases reported through HMIS and IDSR may not be concordant due to differences in reporting time periods (e.g., monthly HMIS reporting versus weekly IDSR reporting), indicator definitions (country-dependent), and the number of facilities reporting into each system. In general, the HMIS is the preferred system for PMI support; however, the IDSR may be more appropriate in low-endemic areas for timely detection of unexpected changes in malaria that may indicate an epidemic.

The concern for many PMI-supported countries at this time is that data collected by health facilities (public, private, and community) and reported through the RHIS are not of sufficient quality (e.g., completeness, accuracy, timeliness) to be useful for monitoring or planning malaria control activities. Many countries are now utilizing a DHIS-2 software platform that is facilitating the timeliness of reporting and visibility of the RHIS data.<sup>152</sup> Issues of completeness and accuracy remain, but this should not keep countries from using information for tracking trends to inform programmatic decision-making while still checking data quality and completeness.

Countries should be supporting an integrated RHIS through MOP funding and technical assistance. In most cases, this will involve the HMIS on a DHIS-2 platform. In most countries, there are multiple stakeholders involved in these efforts. PMI should participate in necessary discussions with this broader set of stakeholders and promote the needs of malaria programs and identify opportunities for supporting activities that focus on malaria data, while assuring the stakeholders that our efforts also benefit the entire system. PMI should not be the sole funder of integrated reporting systems and PMI investments may be influenced by the ability to leverage other donors' support. Depending on country needs, capacity, and other donor activities, country teams may need to determine an appropriate balance of PMI support across routine systems in a country.

#### *Targeted approach for strengthening RHIS*

Resource constraints and the large scale of RHIS strengthening needs will prompt most countries to consider a targeted approach to RHIS support. A targeted approach refers to the following aspects of PMI support for RHIS strengthening: prioritization of passive surveillance in higher-burden areas of the country, selection of high-impact strengthening activities, and a phased

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<sup>152</sup> Note that there may be multiple reporting tools feeding into one reporting system. For example, the DHIS-2 is a common HMIS platform for many countries, and is capable of collecting, transmitting and reporting on a number of different diseases and frequencies. In some countries, the IDSR may also use the DHIS-2 platform.

approach to implementation across districts and facilities. In most instances, initial support should focus on districts with moderate/high malaria burden and overlap with other PMI-supported interventions where it will be important to monitor changes in burden, such as the addition or withdrawal of IRS and the monitoring of case management interventions. As targeted districts and facilities reach the end of their phased period, additional districts and facilities may be selected. The long-term goal of this targeted approach should be to strengthen RHIS and build capacity across all areas nationally in coordination with other partners. The time period of each phase should be determined based on country context and in collaboration with the MOH, NMCP, and all partners.

### *Activities supported*

PMI support for RHIS activities may include those in Box 1. No one partner can support everything that needs to be done in RHIS, but this list of activities can be used to identify gaps and ensure support for all activities across partners.

### **Box 1: SM&E activities recommended and supported by PMI at different administrative levels**

<p><b>Central Level</b></p> <ul style="list-style-type: none"> <li>● Register, tools (e.g., checklists, indicator glossary), job-aids (design, indicators, definition of data elements, data dictionary, system support)</li> <li>● Data quality assessments (separate from supervision – funding for travel to lower levels)</li> <li>● Program monitoring and technical assistance (funding for travel to lower levels)</li> <li>● Training (funding for central level to conduct training at lower levels, capacity building (i.e. on the job training for central level staff))</li> <li>● Human resources (secondment of person in NMCP for SM&amp;E, office/team for SM&amp;E)</li> <li>● Data Use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making)</li> <li>● Policy guidelines and coordination (updating policies, guidelines, supporting sub-committee meetings, supporting participation in sub-committee meetings)</li> <li>● External relations/communications/outreach (support travel to international meetings and publications)</li> <li>● Support to annual operational plans for national malaria program</li> <li>● Desk review to catch “logic errors” in the system (provide TA to catch logic errors)</li> </ul> <p><b>Admin1 (regional-equivalent)</b></p> <ul style="list-style-type: none"> <li>● Registers (warehousing, printing, distribution)</li> <li>● Data quality assessments (separate from supervision – funding for travel to lower levels)</li> <li>● Program monitoring and technical assistance (funding for travel to lower levels)</li> <li>● Training (funding for admin 1 staff to conduct training at lower levels, capacity building (i.e., on the job training for admin 1 level staff))</li> <li>● Human resources (secondment of person for malaria SM&amp;E, office/team for SM&amp;E)</li> <li>● Data use (analysis, interpretation, visualization (dashboards, bulletins), dissemination/feedback to lower levels, decision-making)</li> </ul>
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- 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)
- 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)
- 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, and feedback. These activities also occur at different levels of the health care system. Thus, level of effort will vary depending on the status of implementation of the RHIS. A country that has just rolled out a DHIS-2 platform will need to focus primarily on data collection and processing. A country with 90% reporting would put additional effort into interpretation and use, while continuing to strengthen quality and timeliness of data collection. The intent would be to have a partner-coordinated, phased plan that strengthens the national RHIS over time.

#### *Implementation*

Data of good quality from most facilities is more useful than perfect data from a few. The updated PMI strategy includes a focus area on improving capacity to collect and use information.

With resources available, this scale-up must be a phased approach. Facility- and community-level surveillance support should be part of a larger strategy targeting entire districts in a phased, partner-coordinated roll out, with PMI focused on districts with moderate/high malaria burden and other PMI-supported activities. The latter approach will also help build capacity at the district level for data use and decentralized decision-making.

PMI supports a phased and progressive approach to RHIS strengthening that encompasses strengthening activities implemented across individual clinics, as well as at district and regional levels, to improve data use. Implementation in individual health facilities should reflect an overall strategy to eventually cover an entire district or region, rather than several sites in isolation. PMI does not support sentinel sites, as defined by WHO, which are “established for the purpose of providing representative data, and deliberately involves only a limited network of carefully selected reporting sites.”<sup>153</sup> However, in the absence of a proven optimal strategy, PMI supports a range of RHIS-strengthening models. The timeframes for supporting RHIS strengthening at each facility will vary and must be guided by local circumstances. Evidence for RHIS strengthening should be presented in the MOP to document progress in performance and geographical coverage. Such evidence could be quantitative (e.g., numbers trained in specific activities or skills, changes in DHIS-2 coverage, numbers of facilities reporting to RHIS, or completeness of reporting to RHIS) or qualitative (e.g., instances of staff from supported facilities designing or leading SM&E training activities, or plans for supported facilities to train or advise other facilities). An essential component of documenting progress is clear documentation of denominators. For example, activities targeting the district level should include the total number of districts in the country, the number of districts intended to be reached by the PMI-funded intervention and those covered by other government or donor funds. In order to achieve the largest impact, emphasis should be placed on adding or expanding target areas.

To avoid potential confusion with support for sentinel sites or clinical strengthening, PMI requests only using the term RHIS strengthening (and not terms like “enhanced surveillance” or “malaria reference centers”). This does not mean that those sites will no longer be supported but that the MOPs should be clear in describing the overall strategy for RHIS strengthening efforts aimed at facilities, and how this will 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

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<sup>153</sup> [http://www.who.int/immunization/monitoring\\_surveillance/burden/vpd/surveillance\\_type/sentinel/en/](http://www.who.int/immunization/monitoring_surveillance/burden/vpd/surveillance_type/sentinel/en/)

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.)

### *Parallel malaria-specific efforts*

For surveillance purposes, PMI has supported both parallel malaria-specific surveillance systems and parallel malaria reporting systems. For clarity, here is a brief explanation of the difference between the two:

- **Parallel malaria-specific surveillance system:** This is a system operating outside of the RHIS used to collect specific malaria indicators. These systems employ their own data collection tools, reporting tools, management, and supervision structures. Sentinel sites, as supported by PMI in the past, are an example of such systems. PMI support to these systems in the past was important because routine data on malaria cases and deaths were not widely available from other sources. As routine systems have improved over time (with PMI and other partner support), PMI will no longer support parallel systems. The exception to this guidance is when RHIS (e.g., HMIS) is not functional or the data are of such poor quality that they cannot be used to inform programmatic decision-making. In such cases, supporting a parallel malaria-specific surveillance system could be a temporary solution as part of a larger strategy to strengthen RHIS. The decision to support or develop a parallel system should be clearly justified and made in consultation with the PMI Headquarters SM&E Team.
- **Parallel malaria reporting structure:** This is an alternate reporting route for RHIS malaria data to ensure the data are received by the NMCP. In some countries, it has been difficult for the NMCP to access routine data from the HMIS or IDSR in a timely manner (or at all). In such circumstances, PMI may support the NMCP to develop a reporting “work-around” where districts or facilities report routinely collected malaria data directly to the NMCP in addition to the formal reporting mechanism for the RHIS. As above, PMI may provide this support as a temporary solution to NMCP data access issues, but again, only as part of a broader strategy to strengthen RHIS. The decision to support or develop a parallel reporting structure should be clearly justified and made in consultation with the PMI Headquarters SM&E Team.



In settings of low malaria burden, additional considerations for malaria surveillance strengthening may be warranted:

- **Epidemic-prone areas:** In areas with low malaria burden, if the HMIS cannot be adapted or the IDSR is not functional, a parallel system that reports on malaria cases more frequently than monthly may be required to detect sudden upsurges that could indicate an epidemic. As timeliness of reporting is critical, epidemic detection systems should be based on at least weekly summary reporting from facilities. Another key component is setting appropriate thresholds so that every seasonal increase isn't investigated. In most cases, it would be optimal for a country to build a malaria epidemic surveillance system into an existing reporting system such as the HMIS or IDSR, rather than establishing a stand-alone malaria epidemic detection and reporting system.

Countries should note that epidemic detection systems are meant for **LOW** burden areas. Moderate/high malaria burden areas maintain levels of immunity that make epidemics much less likely. That doesn't preclude an upsurge in malaria cases in these areas. However, rapid detection and response are typically not required, but rather adjustments to malaria control interventions may be necessary. Countries should not use limited resources to investigate "outbreaks" in moderate/high burden settings.

- **Elimination:** In situations where a country has transitioned into the elimination phase, either nationally or sub-nationally, a malaria-specific surveillance system may become necessary because individual case-level data is required to facilitate case investigations. Please see the **Elimination** chapter for more information.

Activities in support of malaria-specific surveillance may include surveillance system development, training, supervision, and communications. The decision to support malaria-specific surveillance systems in addition to routine information systems (HMIS/IDSR) should be informed by country context (e.g., need for epidemic detection, pre-elimination considerations, leveraging other donor support). Implementation must be thoughtfully and realistically conceived and closely monitored to adjust and revise the approach as needed. PMI experience has shown that establishing such systems is often challenging and resource-intensive. In settings where routine data are already of poor quality, a separate surveillance system will have to overcome the same issues: lack of capacity, poor infrastructure, and competing priorities for healthcare workers, among others.

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

## *Population-based surveys*

### *National-level household surveys*

For PMI SM&E needs, conducting a national-level household survey, within established survey timelines set by the Ministry of Health and other partners, is recommended to assess coverage of interventions and, when needed, estimates of malaria prevalence and ACCM. 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. The type of national-level household surveys supported by PMI will generally be a MIS, DHS, or MICS that includes the standard malaria module. While PMI has typically funded an MIS in full or in partnership with the Global Fund, the contribution from PMI to a DHS or MICS has typically ranged from \$350,000-\$500,000 but there are increasing requests from missions for larger contributions to the DHS or MICS. In light of these requests, the PMI contribution to the DHS or MICS should be comparable to the contributions from other health elements (MCH, PRH, NUT, etc.) at the country mission. In recent years, the frequency of such surveys has increased as donors seek evidence of the impact of their investments. There is also an increasing trend (not supported by PMI) towards removing malaria modules from DHS or MICS surveys and advocating for a separate MIS the same year or within 18 months of the DHS/MICS. If a DHS or MICS is planned for a given year, PMI should support it and ensure that the appropriate malaria questions have been included, rather than supporting a separate MIS during the same year. If appropriate, the inclusion of biomarkers in these surveys may be negotiated with the survey planning teams. PMI does not support national-level household surveys that collect malaria indicators more frequently than every two years, regardless of donor source.

Some NMCPs and partners are requesting that national-level household surveys be expanded to obtain estimates with sufficient statistical power for sub-regions or population sub-groups (e.g., school-age children or people over 15 years of age). Per RBM Monitoring and Evaluation Reference Group (MERG) 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-MERG-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-MERG currently do not support such survey expansions. If the NMCP and/or PMI country team believes it needs such estimates and is requesting PMI support, the PMI in-country team is asked to consult with the PMI Headquarters SM&E Team. In some situations, other cross-sectional survey methodology may be more appropriate.

### Biomarker measurements in population-based surveys

The MIS includes measurements of parasitemia and anemia while the DHS includes anemia as part of the nutrition module but does not routinely include parasitemia. The UNICEF MICS does not routinely include any biomarkers, but technical assistance can be provided to include biomarkers to the MICS.

PMI supports parasitemia testing in children 6-59 months of age in countries with a national prevalence estimate of >3%. In general, PMI does not support parasitemia testing during household surveys outside of this age group, with the following considerations:

- PMI does not recommend parasitemia testing below six months of age. The number of children under six months of age that test positive for malaria parasites would be very small.
- Adding other age groups (i.e., school-age children, pregnant women) to be tested would make the survey process more labor-intensive and risk compromising the quality of the survey.
- Gaining access to school-aged children (5-14 years old) can be logistically difficult and costly. Often these children are at school when the surveyors come by the house, requiring repeat visits. The children that are at home may be the sick children, resulting in selection bias.
- Testing pregnant women for malaria parasites during household surveys raises ethical concerns and requires a much larger sample size to produce meaningful estimates. Survey protocols require appropriate treatment with ACTs for anyone testing positive for malaria during the survey. If women of reproductive age (15-49 years) are included in surveys, it presents the possibility of pregnant women in their first trimester (who do not know they are pregnant or are not disclosing they are pregnant) being treated with ACTs, which are not approved by WHO for treatment during the first trimester of pregnancy.
- PMI supports the guidance provided in the RBM MERG Household Survey Indicators for Malaria Control document regarding the use of RDTs ([http://www.rollbackmalaria.org/files/files/working-groups/MERG/Reference%20documents/tool\\_HouseholdSurveyIndicatorsForMalariaControl.pdf](http://www.rollbackmalaria.org/files/files/working-groups/MERG/Reference%20documents/tool_HouseholdSurveyIndicatorsForMalariaControl.pdf)). Parasite prevalence should be based on the results of a high quality RDT where *P. falciparum* accounts for nearly all infections ( $\geq 90$  percent). PMI does not support the use of multi-species RDTs in surveys.

If a planned MIS or DHS contains parasitemia testing in age groups outside 6-59 month olds, PMI will support the survey (provided it has been approved by the PMI Headquarters SM&E Team), but will not fund the testing in the additional age groups.

As countries enter the pre-elimination phase of malaria control, the focus will shift to heightened surveillance systems that provide continuous information, rather than periodic nationwide

household parasitemia surveys. **Therefore, PMI recommends that in countries where national parasite prevalence in children under 5 years of age is below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued.** Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains greater than 3% in other regions.

### *Combined national-level surveys*

While collaboration with other groups conducting large-scale health surveys (such as a national census or an AIDS Indicator Survey) can be mutually beneficial, past experience has shown that there can be serious challenges when surveys are combined. The logistics for planning surveys is complex and combining surveys increases the complexities and introduces additional coordination issues across partners and technical areas, resulting in increased sample sizes, delayed surveys, and impacting overall data quality. If combined surveys are planned, it is recommended that PMI in-country teams consult with the PMI Headquarters SM&E Team to help negotiate with other stakeholders to ensure that PMI needs will be met, including an agreement such as a memorandum of understanding that outlines PMI's participation in the review of preliminary malaria data, as well as receipt of the full report and final dataset within an agreed-upon time limit.<sup>154</sup> The standard malaria modules in the DHS, MICS, and MIS surveys are interchangeable. If concerns exist about the quality of any of these surveys, country PMI teams are encouraged to speak with the PMI Headquarters SM&E Team in the early stages of survey planning.

### *Special cross-sectional surveys*

Special cross-sectional surveys (e.g., post-LLIN campaign surveys) can be designed to answer programmatic questions that pre-planned national-level household surveys cannot. Issues related to timing or a need for detailed data that cannot feasibly be added to a DHS or MIS may necessitate a separate survey. These surveys may focus on particular sub-populations or geographic areas of programmatic interest. They may, for example, be used to assess the result of a particular intervention strategy (e.g., LLIN ownership after a sub-national LLIN distribution campaign), or malaria burden in a sub-group of individuals (anemia and parasitemia in school-age children), or utilize malaria measures other than parasitemia or RDT (e.g., serology or PCR). PMI only recommends these surveys when a clear and necessary programmatic question needs to be answered and no other suitable data source for addressing the question exists. If the timing of a larger planned survey, such as DHS or MIS, coincides with the desired timing of a special survey, every effort should be made to utilize the planned DHS or MIS. Special surveys should

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<sup>154</sup> The DHS Program includes an MOU for all surveys (DHS and MIS) that agrees to provide public access to the dataset after the national dissemination of the final report. In surveys that are implemented by other partners and partially or fully funded by PMI, an MOU should be developed and negotiated for access to the dataset.

be timed for optimal data collection based on the programmatic question they are intended to answer and should not be repeated annually.

If special surveys are proposed in country MOPs, country teams should provide concise descriptions of the activity that outline the programmatic question, scope, scale, and timing of the survey, in addition to how the information would be used to improve program implementation. A clear determination should be made whether the survey proposed is operations research; and in such cases coordination with the PMI Headquarters Operational Research Committee should be done.

### *Health facility-based surveys*

Nationally-representative health facility surveys (HFS) are intermittent, comprehensive evaluations of health system function and are primarily used for program monitoring: establishing a baseline and assessing which aspects of the program require intervention or policy change, and then monitoring changes in relevant indicators after the intervention or policy has been implemented. Health facility surveys are useful in situations where routine information systems and household surveys do not provide all of the necessary information on case management practices, system readiness, and training and supervision to meet programmatic needs of the NMCP or PMI. As of 2019, there is no standard malaria-specific HFS. Health facility surveys should not be used as replacements for the HMIS and SM&E efforts should focus on strengthening HMIS; however, when facility readiness/performance data is not available, periodic HFS should be considered. **Investigations conducted in health facilities in response to a specific problem would not be considered health facility surveys. For example, discrepancies between actual case management practices and HMIS reporting are best investigated through smaller-scale investigations than through a nationally-representative HFS.**

**Methodology:** HFS typically capture cross-sectional data from health facilities on several aspects of the health system including availability of commodities, appropriateness/quality of case management, data reporting, record reviews, diagnostic capacity, health worker training, and other indicators critical to malaria programs. The type of information required, the level of detail, and other factors will determine the appropriate HFS methodology to be used. A HFS may also include assessment of data quality and reporting, although it is not part of some standard protocols.

**Scope:** Endemic countries should consider nationally representative HFS in cases in which PMI is only working in part of the country or only parts of the country are endemic, sub-national HFS can be considered.

**Timing:** As a general rule HFS should not be repeated more than every 2-3 years, depending on the information required. More frequent HFS may be considered on a case-by-

case basis but there should always be enough time between HFS to allow for interventions or policy changes to produce measurable changes. When possible, HFS should be carried out during the malaria season to obtain the most reliable assessment of malaria service readiness.

**Costs:** Costs will vary widely, from \$150,000 to over \$1 million depending on the sample size and method. In general, because health facility surveys can be very comprehensive and include many other health delivery systems, PMI should strive to work with other partners to fund HFS.

**Integration:** Children under five years of age with fever are evaluated in health facilities using integrated case management protocols. When a HFS includes an observation or re-examination module, case management of children should be observed and cases re-examined using an integrated protocol. Commodities, health worker knowledge and materials for IPTp should be included in any HFS. In some situations, commodity or other data for other illnesses seen in facilities may be requested by other programs. As long as costs, timing and complexity of the HFS are not increased, integration of that type may be considered. Co-financing should be sought from other programs requesting data from a PMI-supported HFS.

**Outpatient/inpatient:** An HFS can include outpatient and/or inpatient assessments. Most HFS that PMI supports are outpatient assessments for which standardized protocols already exist and can be applied with minor adaptation. Inpatient assessments are generally more complex and require additional expertise from trainers, surveyors and supervisors, as well as data processing and interpretation. Inpatient care can vary widely by type/level of inpatient facility making their assessment more complicated. Consult with the SM&E Team when considering inpatient assessments.

**Modules:** The type of modules used in a HFS will depend on objectives, but may include:

- Health worker and/or supervisor interview
- Health worker and/or laboratory technician observation
- Record review
- Re-examination of sick child
- Facility readiness checklist
  - Infrastructure
  - Diagnostics
  - Medications
  - Reporting forms
- Caretaker exit interview
- Surveyor observations
- Mystery patients

In some situations, an additional module on data quality and reporting may be included.

**Reports:** HFS data (e.g., commodities) can rapidly become non-actionable, so consideration should be given to generating analyses and reports as fast as possible. Generally, the larger or more complex the survey, the longer it may take to generate a report.

**If you are planning an HFS for the first time, consult with the SM&E Team for additional information.**

### *Examples of health facility surveys*

There are several types of health facility survey protocols, which vary in the aspects of the health system on which they focus, the overall cost and complexity, and how the results can be interpreted. For PMI purposes, HFS that produce estimates quickly – within three to six months – should be favored as commodity and case management data become increasingly non-actionable if there are significant delays between the survey and the sharing of results.

#### *Service provision assessment*

Service provision assessment (SPA) surveys examine the supply side of health care and the strengths and weaknesses of a country's public and private services. A SPA is one of the most complex facility surveys and collects data from a large sample (often in the hundreds) of health facilities on the readiness and availability of specific health services and commodities as well as quality of services. The SPA focuses on nine key services: (1) child health; (2) maternity and newborn care; (3) family planning; (4) sexually transmitted infections; (5) HIV/AIDS; (6) malaria; (7) tuberculosis; (8) basic surgery; and (9) non-communicable diseases. The SPA includes assessment of health provider practices in each of the key services through direct observation, health worker interviews and exit client interviews. Instruments typically used in a SPA are:

- Health worker interview
- Caretaker exit interviews
- Health worker observation protocols
- Facility inventory

The tool can be found at: <http://dhsprogram.com/What-We-Do/Survey-Types/SPA.cfm>

#### *Service availability and readiness assessment*

Service availability and readiness assessment (SARA) surveys are designed to assess and monitor the service availability and readiness of the health sector and to generate evidence to support the planning and managing of a health system. The SARA generates tracer indicators of service availability and readiness. The SARA has been developed by WHO in conjunction with global partners to fill critical data gaps in measuring and tracking progress in health systems strengthening. While the SARA is not malaria-specific, it is possible to include a patient exit

interview module to assess malaria case management practices; an optional data quality assessment module can also be added. Instruments typically used in a SARA are:

- Staffing matrix
- Inventory of inpatient and observation beds
- Facility infrastructure audit
- Inventory of available clinical services
- Diagnostic capacity assessment
- Inventory of medicines and commodities
- Interviewer's observations

The tool can be found at: [http://www.who.int/healthinfo/systems/sara\\_introduction/en/](http://www.who.int/healthinfo/systems/sara_introduction/en/)

*Integrated management of childhood illness health facility surveys (IMCI HFS)*

Integrated management of childhood health facility surveys collect health facility data exclusively on childhood diseases including pneumonia, diarrheal disease, and febrile illnesses (malaria, including trigger points for management and referral for severe malaria). This survey produces findings within 12 weeks of start of implementation and can be adapted to different sample sizes. Instruments typically used in the IMCI HFS are:

- Health worker observation checklist
- Exit interview – caretaker of child
- Re-examination of sick child
- Equipment and supply checklist
- Health worker interview (optional)

The tool can be found at:

[http://www.who.int/maternal\\_child\\_adolescent/documents/9241545860/en/](http://www.who.int/maternal_child_adolescent/documents/9241545860/en/)

*End-Use verification tool*

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

## Evaluation

Evaluation is a critical component of any national malaria control program and should be integrated into national SM&E strategic plans. PMI supports both program and impact level evaluations at the country level, however there are a number of considerations to take into account when programming funds for evaluation activities.

As part of overall malaria control impact evaluations, PMI generally does not support evaluations aimed at establishing/researching a WHO-recommended specific intervention's impact on morbidity or mortality (WHO recommended malaria interventions include but are not



limited to IRS, ITNs, IPTp, Case Management, and SMC). PMI is based on a principle of implementing **already-proven interventions** and thus does not support individual country programs to test/research any one intervention or package of interventions to assess its impact on malaria morbidity or mortality. Also, given PMI's success in increasing coverage of multiple interventions across countries, conditions do not lend themselves easily to evaluate the impact of single interventions.

As interventions are being scaled-up, PMI encourages evaluations in countries where these interventions are not resulting in the expected outcome. These evaluations can help to identify ways to improve the effectiveness, coverage, or service delivery of individual interventions.

### *Program evaluation*

There may be a number of times in a program's lifecycle when an evaluation is necessary to inform further programming decisions. Some examples of when a program evaluation might be useful include evaluating a pilot to inform decisions about scale-up of interventions, evaluating the effectiveness of one programmatic approach against another, or evaluating project achievements at the end of an activity before a programmatic redesign process.

Malaria program reviews per WHO methodology include program evaluation components and are generally supported by PMI. Malaria program reviews should be carefully planned and coordinated with all partners (ideally timed to precede a country's new 5-year National Malaria Strategic Plan), last less than one year, not be repeated more frequently than every four years, and produce actionable data and information. No more than \$100,000 of PMI resources should be budgeted in total for a malaria program review.

<https://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformancemanual/en/>

### *Impact evaluation*

Evaluations of impact are generally good practice; however, PMI will not be funding these evaluations in every country. Impact evaluations are used to determine whether supported activities have had the desired effect on morbidity and mortality under operational conditions. Generally, evaluations of impact should be carried out only when interventions have reached sufficient coverage to expect impact. Globally-accepted methodologies preferably sanctioned by the WHO or the RBM MERG

([https://endmalaria.org/sites/default/files/Framework%20for%20Evaluating%20National%20Malaria%20Programs%20in%20Moderate-%20and%20Low-Transmission%20Settings\\_FINAL\\_tr-19-334.pdf](https://endmalaria.org/sites/default/files/Framework%20for%20Evaluating%20National%20Malaria%20Programs%20in%20Moderate-%20and%20Low-Transmission%20Settings_FINAL_tr-19-334.pdf)) should be used to ensure consistency and comparability across time and countries.

Evaluations of impact should be transparent and participatory. Many stakeholders, both within malaria control and without, should be encouraged to participate in the design, analyses, and production of reports.

The PMI Headquarters SM&E Team will reach out to countries that should consider an evaluation of impact to help plan and support it.

## **Activities No Longer Supported By PMI**

### *Demographic surveillance system sites*

PMI does not provide direct support for demographic surveillance sites to monitor births, deaths, and health in geographically-defined populations continuously over time. It is possible, however, that PMI support might provide some limited support for data analysis of existing data in the context of impact evaluation activities.

### *Verbal autopsies*

Following several pilots of the use of the verbal autopsy procedure, PMI has taken the decision to no longer use verbal autopsies to assess impact on malaria-specific mortality. The specificity and sensitivity of verbal autopsies for several fever-associated diseases, such as malaria, is low and verbal autopsies cannot be used to determine malaria-specific mortality within acceptable bounds.

## SM&E Appendix 1: System Requirements at Various Health System Levels During Control and Elimination Phases

	Control (SPR >5% amongst all febrile patients)	Pre-elimination (SPR <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
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	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
District / Province	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
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

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# OPERATIONAL RESEARCH

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## \*New/Key Messages\*

**New OR prioritization process:** Each year the U.S. Global Malaria Coordinator will announce the new OR priorities. Country teams will discuss research ideas and receive feedback from HQ backstops/technical teams. Principal investigators of the approved ideas are invited to submit a CN and Research Determination form. A detailed budget using the PMI template included in this guidance is required when submitting the protocol for OR Committee Review.

**New Timeline for OR activities:** When OR activities receive funds from multiple sources, concept notes should clearly explain which study components are being covered by PMI (and their specific costs) and summarize the co-funding from other sources.

**OR Committee role in the development and implementation of OR studies:** The OR Committee – as an advisory committee – is not responsible for handling study implementation or study roll-out challenges. PIs of PMI-funded studies and their respective implementing organization/institution 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 members will not be involved in study implementation and/or negotiations of implementing partners in their OR Committee capacity.

OR Committee members can suggest technical input on an informal basis in their technical capacity as a member of a specific PMI interagency technical team, but such advice should not be considered OR Committee requests or a substitute for OR Committee review of a PMI OR concept note or protocol. If an OR Committee member is involved in study design or implementation, they are recused from Committee deliberations and decisions regarding the study in question.

**Research Determination:** All PMI-funded OR activities must be reviewed to determine whether they are research involving human participants.

## Introduction

Operational Research (OR) plays an important role in improving the successful implementation of PMI malaria control strategies and in achieving the PMI goal. Since 2006, PMI has supported numerous OR studies addressing a range of programmatically-relevant topics and continues to do so in support of the *PMI Strategy 2015-2020*. Appropriate questions addressed by OR studies include how to improve scale-up of interventions, how to further increase effectiveness of existing interventions, how to implement combinations of these interventions in sequence or in parallel, and how the interventions should be tailored to different epidemiological settings.

Additional important questions include how to implement interventions in the most cost-effective manner, how to preserve the effectiveness of proven interventions threatened by resistance or other risks, and how best to incorporate promising new interventions and innovations that have the potential to further reduce malaria morbidity and mortality suggested by an available body of evidence, including in areas where some of the proven interventions currently available are either not sufficiently effective or where implementation is not feasible. PMI resources are not used to support research that is in proof of concept and/or early phase efforts to build the initial evidence base for a potential future intervention.

Please see **PMI Policy** for a description of the PMI OR leadership and management structures (PMI OR Coordinator, Interagency OR Committee and Management Team) and governance structures for PMI OR decision-making. The guidance included below focuses on objectives and priorities, guiding principles and processes for PMI country teams and PMI headquarters interagency technical teams proposing PMI MOP (country budget) or PMI core-funded (headquarters budget) OR activities.

## PMI OR Objectives

PMI will support program- and policy-relevant OR and program evaluation that will:

- Improve effectiveness of existing interventions and increase scale-up and quality, including assessing combined interventions (e.g., LLINs and IRS)
- Evaluate ways to mitigate insecticide and drug resistance
- Identify and assess improved and cost-effective approaches to monitoring changes in malaria epidemiology, particularly for documenting impact of malaria control efforts
- Identify and assess approaches to improve the capacity of health systems to optimize delivery and quality of malaria interventions
- Assess new interventions that offer the potential for use by PMI-supported programs in the near future
- Assist in optimizing program efficiency by addressing bottlenecks in malaria prevention and control

## Funding Sources and Channels/Mechanisms for PMI Operational Research

Funding for PMI OR activities may come from two places within the PMI budget:

- **PMI country/MOP budgets:** PMI OR studies funded with country MOP funding are generally conceived and designed by PMI country teams in consultation with NMCPs and local partners, and they are frequently implemented by local research groups. These

tend to be shorter-term studies (duration of 12-24 months). The amount of country funding proposed for country-specific OR activities vary by country and by year.

- **PMI core funds allocated for OR priorities:** PMI OR studies conceived of and funded centrally with PMI core funding generally address broader issues applicable across the initiative and tend to be larger studies with higher budgets than country-generated OR activities. They may involve two or more PMI-supported countries and/or require several years to complete. The amount of core funding made available for priority OR activities varies from year to year depending on several factors including the overall total PMI budget, other PMI core budget priorities, the number of interagency core funded concept notes proposed and prioritized for funding, and the incremental funding needs for multi-year studies funded in previous years.

Most PMI support for OR is in the form of funding directed to implementing partners to carry out the research study. PMI support also includes support for commodities supported outside of the OR implementing partners budget (see “Commodities for OR” section below) and interventions (i.e., ITN distribution or IRS implementation funded outside of the OR implementing partner budget) and PMI headquarters and field staff time. Please consult the section titled “What is considered under PMI support for OR?” for details.

Whether the source of funding for PMI-supported OR studies is core- or country- (MOP) funding, a variety of mechanisms and technical collaboration and oversight by PMI staff are available to carry out PMI funded research. Which mechanism is selected depends on a variety of factors including the research question, country partner context, level of engagement of PMI technical staff, etc.

Options include: (1) USAID country bilateral and central implementing partner mechanisms including USAID mechanisms that provide direct funding to local research institutions; (2) research collaboration involving CDC and/or USAID headquarters technical staff and a USAID country bilateral or central implementing partner mechanism with PMI staff directly engaged in protocol development, research implementation oversight, data analysis, etc.; and (3) CDC staff working with a local partner through a CDC mechanism accessed through the CDC IAA.

For option (3) above, because the CDC Interagency Agreement (IAA) per congressional requirements includes policy restrictions for USAID appropriated funding to pass to CDC and on to a third party, if the third option is being considered by PMI teams, early discussion is needed to determine whether or not the conditions exist to request an exception and prior approval of an exception request is required before OR study planning moves forward. There have been very few exceptions approved in the last few years. 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.”* In particular, exception requests for PMI supported OR 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. The PMI Coordinator and CDC IAA COR approval are both needed for such an exception. Direct funding of MOH/NMCP/host country governmental institutions (G2G) can be considered only through a USAID G2G mechanism and only following the completion of appropriate financial management system audits etc. Funding MOH/NMCP/host country government institutions (G2G) through CDC with USAID appropriated funding (PMI or all other types of funding) is prohibited by USAID agency-level policy restrictions (See **PMI Policy, ‘CDC Interagency Agreement’** section).

PMI co-funding of OR activities with other donors and organizations also occurs and is highly encouraged. One example is a cost-effectiveness study of vector control interventions in Mozambique, co-funded by UNITAID through IVCC and PMI. This type of cooperative research effort is encouraged during the review process, especially for studies whose results are applicable to a new global policy recommendation or one under revision where a larger body of evidence will be desired.

## **PMI OR Priority Setting Process**

Beginning in FY2018, the U.S. Global Malaria Coordinator announced a new process for setting OR priorities. The new OR priority setting process will create a strategically narrow, focused set of scientific and operational research priority questions applicable to both core and MOP funds, based on headquarters senior management, technical team, and country consultation will be determined each year. The new OR priority setting process will also include a defined budget and a single review period for approved core and MOP funded OR each year.

PMI technical teams will be requested to convene each year to identify, discuss, and prioritize critical operational and implementation bottlenecks that require core OR funds. Each technical team will be asked to submit one priority item to the OR management team in mid-November. PMI interagency technical teams will work with country teams to develop ideas for OR activities that address county-specific OR needs. The list of proposed ideas for core-funded and MOP-funded priorities submitted by the PMI interagency technical teams and country teams will be discussed at the PMI Senior Management meeting in November. The U.S. Global Malaria Coordinator will announce the approved core and MOP-funded priorities and set the budget for each priority in December.

## Timeline for the OR Process

### Core-Funded OR

Aug-June	July-Oct	Nov 15	Pre-ASTMH (late Nov)	Dec
<p>OR mgmt and PMI leadership discuss guiding principles to technical teams on core funded OR ideas</p> <p>"Think tank" session to discuss data (QR, external) to help generate OR ideas and/or guidance to HQ/country teams</p>	<p>HQ technical teams identify priority ideas focusing on large scale, multi-country, and possibly multi-donor studies</p>	<p>Technical teams submit priority OR ideas to OR management team</p>	<p><b>Pre-CN idea vetting process:</b></p> <ul style="list-style-type: none"> <li>OR mgmt team reviews OR ideas</li> <li>OR mgmt team shares top ideas with PMI senior mgmt</li> </ul>	<p><b>OR prioritization process:</b></p> <ul style="list-style-type: none"> <li>PMI coordinator announces OR priorities</li> <li>Approved ideas are invited to submit a CN and Research Determination form</li> <li>OR committee members are assigned to review/provide input</li> </ul>

### MOP-Funded OR

MOP visits: Aug-Nov	One month after MOP (by Nov 15)	End of Nov	Dec	TBD
<p>Country teams discuss ideas and receive feedback from HQ backstops/technical teams</p>	<p>OR ideas are submitted to the OR mgmt team</p>	<p><b>Pre-CN idea vetting process:</b></p> <ul style="list-style-type: none"> <li>OR mgmt team reviews OR ideas</li> <li>OR mgmt team shares top ideas with PMI senior mgmt</li> </ul>	<p><b>OR prioritization process:</b></p> <ul style="list-style-type: none"> <li>PMI coordinator announces OR priorities</li> <li>Approved ideas are invited to submit a CN and Research Determination form</li> <li>OR committee members are assigned to study to review and provide input</li> </ul>	<p>CNs are approved by PMI leadership to proceed to protocol development</p>



## Guidelines for Selection of OR Activities for PMI Funding

The following guiding principles were developed to assist PMI interagency technical teams and country teams when considering ideas for OR priority submission (MOP or core-funded). These guidelines apply to all PMI-funded OR activities. In general, as previously mentioned, OR research funded with PMI country-specific MOP funding responds to country-specific priorities and needs while core-funded OR typically addresses broader issues that are relevant across PMI's programs. Core-funded OR may be conducted across multiple countries and may address fundamental questions to achieve optimal impact from proven interventions.

### *Guiding principles for country-led (MOP-funded) research:*

Country-led (MOP-funded) study ideas should be oriented towards program evaluations to address:

1. Coverage of population infected/at-risk
2. Quality of intervention
3. Efficiency in intervention delivery

Country teams can also propose other ideas, but should provide justification on the broader applicability of anticipated study results.

### *Guiding principles for core-funded research*

Core-funded study ideas should focus on:

1. Reducing remaining malaria transmission and disease burden
2. Testing effectiveness of new or evolved priority interventions and strategies
3. Exploring new metrics and mechanisms to assess the impact of interventions

### *Additional considerations*

Additional considerations for OR priority submissions include:

- Is the idea strategically important to PMI (weigh against guiding principles)?
- Which countries are struggling with issues that this research will help address?
- Has this been funded by PMI in the past?
- Are there other parties already doing this research?
- Are there other donors that would be interested in collaborating to fund this?
- What research are other donors funding and how does it relate with our scope?

It is recognized that some high priority OR activities may take several years to complete. Therefore, PMI does not impose restrictions on study length nor likely time from study start to intervention implementation for PMI OR studies. However, when considering which of several high priority studies to fund, the time from study start to likely time of intervention

implementation will be considered, recognizing that research itself can accelerate the timeframe to policy adoption and intervention implementation.

All PMI-supported OR studies, regardless of the implementing partner or funding source, will be reviewed by an interagency OR Committee and monitored and tracked by an interagency OR Management team with overall oversight by the PMI OR Coordinator to ensure efforts are coordinated and support PMI's goal. It is expected that CDC will be a key implementer of PMI-supported OR, as specified in the Lantos-Hyde Act, whether an exception is approved to rely on CDC staff and their research collaboration with a PMI country local partner or most often through CDC staff research collaboration with the research partner(s) accessed through a USAID bilateral or central mechanism.

## **OR Study Development, Review, and Approval Process: MOP-Funded OR**

### *Key considerations*

- Under the new prioritization process, country teams are encouraged to submit ideas to the OR management team for MOP-funded research according to the “Guiding principles for country-led (MOP-funded) research” (see above).
- OR should be relevant to country needs, completed in a timely manner, and prepared to broadly disseminate/use results within 2-3 years.
- Dissemination plan outlined at the outset ensuring timely sharing of findings for action by NMCP/other implementers and encourage the use of results.
- Country teams establish a process for tracking adoption and implementation of key OR recommendations and application of results at the country level for annual report and other PMI reporting purposes.

### *OR concept development and inclusion in the MOP*

Under the new OR prioritization process mentioned above, up to three MOP-funded research priorities will be announced in December by the U.S. Global Malaria Coordinator each year. Following the announcement of the OR priorities and budget, the OR management team will solicit concept notes from country teams to address the identified priorities. When developing concept notes, country teams should ensure that they will address a pressing country need (i.e. programmatic and/or implementation bottlenecks), are feasible to answer considering the budget and length of time required, align with the country operational research strategy or priorities, and address a PMI-OR priority for that year. Additionally, teams should keep in mind the differences between research (systematic investigation designed to develop or contribute to generalizable knowledge) and program evaluation (systematic investigation designed to assess a specific public health action(s) to improve its outcome and impact). Operational research is not different

in principle from “research”, but is focused primarily on service delivery and effectiveness, feasibility at scale, cost, and other such factors.

For a protocol and budget that is already approved and the country team is requesting additional funds through a reprogramming request, the country team must re-submit the revised protocol and budget to the OR Committee for review and receive approval by PMI senior leadership **prior** to submitting the reprogramming request.

Concept notes will be reviewed by the OR committee and appropriate technical team staff, as needed, during a single review period. Deadline reminders are sent out PMI-wide one month in advance. PMI senior leadership will provide approval for concept notes/budgets progress to the protocol development stage. The OR committee and PMI senior management will no longer conduct ad hoc reviews or approvals of concept notes or protocols.

### ***MOP proposed concept note review***

Once MOP-funded OR priorities are announced by the U.S. Global Malaria Coordinator, the country teams may submit a concept note and budget for review by the interagency OR Committee using the template provided in **OR Appendix 1**. After this stage, study team can be formed once the IP is known. Study teams can be inclusive of PMI staff but not entirely made up of PMI staff. For reprogramming requests for additional funding of approved protocols/ongoing studies due to changes in the study budget, country teams must re-submit the revised protocol and budget to the OR management team for approval by PMI senior leadership prior to submitting the reprogramming request.

Concept notes will first be screened by the PMI Headquarters OR Management Team for completeness within **one week** of submission. Incomplete concept notes will be returned without review. Complete concept notes will be sent to the OR Committee or an appropriate member of an HQ technical team for technical review and feedback and a response returned to the study point of contact (POC) within **four weeks** of the submission due date. Study teams will work with the OR Committee and relevant HQ technical team(s), as appropriate, to submit the concept note for review and approval by PMI senior leadership. Concept notes reviewed by PMI senior leadership can have the following three outcomes:

- **Approved:** PMI senior leadership determines that the proposed study will provide valuable information and is technically sound and approves it for funding. Protocol development may proceed and must incorporate any outstanding questions or issues identified by PMI senior leadership. The full study protocol and budget must be submitted for review by the OR Committee and PMI senior leadership for final approval (**please note, OR Committee review and approval does not substitute or override ethical or institutional reviews**).

- **Resubmit:** PMI senior leadership determines that the concept has significant problems with the study design as proposed. PMI senior leadership recommends that the concept note be revised and resubmitted, providing extensive feedback to help guide revisions. PMI senior leadership and the OR management team will work with the study POC to establish a resubmission and review timeline.
- **Decline:** PMI senior leadership determines that the proposed concept note is not priority or appropriate for PMI funding. Clear feedback will be provided explaining why this conclusion was reached.

### *Protocol review*

Protocols must be submitted to the PMI OR Committee for review prior to submission to relevant Institutional Review Board approval(s). Protocols will be reviewed to ensure the study is technically sound and is consistent with what was proposed in the concept note, including study budget and timelines. Outstanding questions or issues identified by the OR Committee during concept note review must be addressed in the protocol. Any changes to the study research question/objectives, design, methods, etc. that have occurred between concept note approval and protocol submission must be explained. Protocol review feedback will be returned to the study POC within three weeks of the protocol submission due date.

## **OR Study Development, Review, and Approval Process: Core-Funded OR**

### *Key considerations*

- Under the new prioritization process, HQ technical teams country teams are encouraged to submit ideas to the OR management team for core-funded research according to the “Guiding principles for core-funded research” (see above).
- Dissemination plan outlined at the outset ensuring timely sharing of findings for action by PMI/NMCPs/other implementers and encouraging the use of results.
- PI should establish a process for tracking adoption and implementation of key OR recommendations and application of results across countries as applicable.

### *Core-funded concept note development*

#### *Process and approach*

The process and approach for identifying and developing ideas for core-funded OR proposals for core funding will include the following steps:

1. Interagency HQ technical teams submit one OR priority idea to the OR management team for consideration by PMI senior leadership. Submitted OR ideas should align with the “Guiding principles for core-funded research” (see above).

2. PMI senior leadership review proposed OR priorities ideas and announce the current year OR priorities in November.
3. Relevant HQ interagency technical teams and country teams develop concept notes to refine the idea as needed and come to an agreement. If the idea is cross-cutting, all relevant interagency technical teams should be included.
4. Study team submits the concept note to the OR committee for technical review.
5. Study team work with the OR Committee and relevant HQ technical team(s), as appropriate, to submit the concept note for review and approval by PMI senior leadership. Concept notes reviewed by PMI senior leadership can have the following three outcomes:
  - a. **Approved:** PMI senior leadership determines that the proposed study will provide valuable information and is technically sound and approves it for funding. Protocol development may proceed and must incorporate any outstanding questions or issues identified by PMI senior leadership. The full study protocol and budget must be submitted for review by PMI senior leadership for final approval (please note, PMI senior leadership review and approval does not substitute or override ethical or institutional reviews).
  - b. **Resubmit:** PMI senior leadership determines that the concept has significant problems with the study design as proposed. PMI senior leadership recommends that the concept note be revised and resubmitted, providing extensive feedback to help guide revisions. PMI senior leadership and the OR management team work with the study POC to establish a resubmission and review timeline.
  - c. **Decline:** PMI senior leadership determines that the proposed concept note is not appropriate for funding. Clear feedback will be provided explaining why this conclusion was reached.
6. For approved CNs, the PMI senior leadership communicates CN approval to study team.
7. Full study protocol and budget that addresses questions raised by the OR Committee and/or PMI senior leadership during CN review is submitted to OR Committee. PMI senior leadership may:
  - a. **Request that a protocol be revised and resubmitted**
  - b. **Approve a protocol**
8. Upon approval of the protocol and budget by PMI senior leadership, the core-funded OR project is considered active and implementation can begin.

## What is Considered Under “PMI Support for OR”?

All operational research activities receiving PMI support are subject to the OR approval process outlined in this guidance. Support includes use of PMI MOP or core funds by an implementing partner to carry out the study, as well as use of PMI-procured commodities, deployment of PMI interventions for the express purpose of the study, and dedication of PMI field and/or headquarters staff time to the development, implementation, and/or analysis of the study.

## Commodities for OR

For OR studies that require commodities (including RDTs, ACTs, LLINs, lab supplies, etc.), the preference is that country teams procure through PMI's centrally managed supply chain partner. Discussions with the Supply Chain (SC) Team around commodity lead times - inclusive of QC, registration considerations, and any other relevant considerations - should begin as soon as possible, even in advance of formal approval of the concept note. This recommended that orders are placed through the PMI supply chain project ensures quality of the commodities sourced and relies on pre-negotiated pricing etc. whenever possible. Once a concept note is approved, the PMI point of contact(s) must inform the SC Team of the anticipated commodity order and study timeline as soon as possible, to facilitate timely placement of the order and arrival of supplies in country when needed. Contact can be made directly with the SC Team or through the OR Coordinator. The study budget in the concept note should include specific lines and estimated funding allotted costs for commodities that are required as part of the study that will be purchased through the supply chain project. For core-funded OR commodity needs, the estimated funding for commodities outlined in the study budget will be directed to the centrally-managed malaria commodities procurement project. For MOP-funded OR commodity needs, country teams should specify at least two mechanisms for the OR study – the mechanism implementing the research and the PMI centrally-managed malaria commodities procurement project with the estimated commodity costs directed to the commodity procurement mechanism. Similar advance coordination with PMI implementing partners and their respective C/AOR team who will deploy IRS, ITNs, etc. that are a core component of the OR study is required.

**Please note:** Concept notes are still required if a country wants to support an OR study being conducted and funded by another donor by providing commodities procured by PMI funds.

## Study Budget

The OR Committee review of concept notes requesting PMI funds covers technical and budgetary aspects of the concept note. A well-thought out budget (using template provided) 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. Efforts must be made to develop a detailed budget at the concept note stage since study budgets are part of requirements for PMI senior leadership review and approval. Protocols undergo a thorough review by a subset of OR Committee members and a recommendation for approval or disapproval is then made by the PMI senior leadership: protocols are, therefore, approved on the understanding that the budget remains the same as in the concept note.

PMI senior leadership provides approval for a study for its technical integrity and budget. Any changes in the technical approach (including research questions/objectives, design, study sites,

and methodology) or the budget during the implementation requires re-submission and re-approval by PMI senior management. All protocols, unless clearly indicated by the applicant, are approved on the understanding that the budget remains the same as in the concept note.

PMI senior leadership approval is required before additional funds are requested for ongoing studies through reprogramming or action memos for core funded studies.

## **Changes to Approved Protocols/Ongoing studies**

When the technical or financial aspects of the protocols are modified after the initial protocol is approved: The study protocol amendments and the revised budget will be shared with the OR Management Team and PMI senior leadership for approval. Protocols for PMI-funded studies must clearly explain what will be accomplished with the approved PMI funds and not include contingencies that encourage collection of data that can be processed if additional funds become available. The OR Management team needs to be notified regarding any protocol changes as soon as possible to avoid study implementation delays. Similarly, any change of the study budget that is greater than 10% need to be approved by the PMI senior leadership.

## **Co-funding of OR Activities**

When OR activities receive funds from multiple sources, concept notes should clearly explain which components of the study are being covered by PMI and the specific cost associated with these components as well as summarize the co-funding from other sources for the study. Even if contributions are limited to PMI staff time or provision of commodities, these are considered as PMI support and a concept note outlining these contributions in the context of the full study must be submitted.

## **OR Committee Role in the Development and Implementation of OR Studies**

The OR Committee – as an advisory and approval body – is not responsible for handling study implementation or study roll-out challenges. PIs 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 members will not be involved in study implementation and/or negotiations of implementing partners in their OR Committee capacity. OR committee members can provide technical input on an informal basis 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 guidance or a substitute for OR Committee review and approval of a PMI OR concept note or protocol. If an OR Committee member is involved in study design or implementation, they are recused from Committee deliberations and decisions regarding the study in question.

## Responsibilities of the OR Committee and OR Management Team

The Senior Management Team (U.S. Global Malaria Coordinator, Deputy Coordinator, USAID Malaria Division Chief, and CDC Malaria Operations Unit Lead) is responsible for providing overall annual guidance and prioritization of OR.

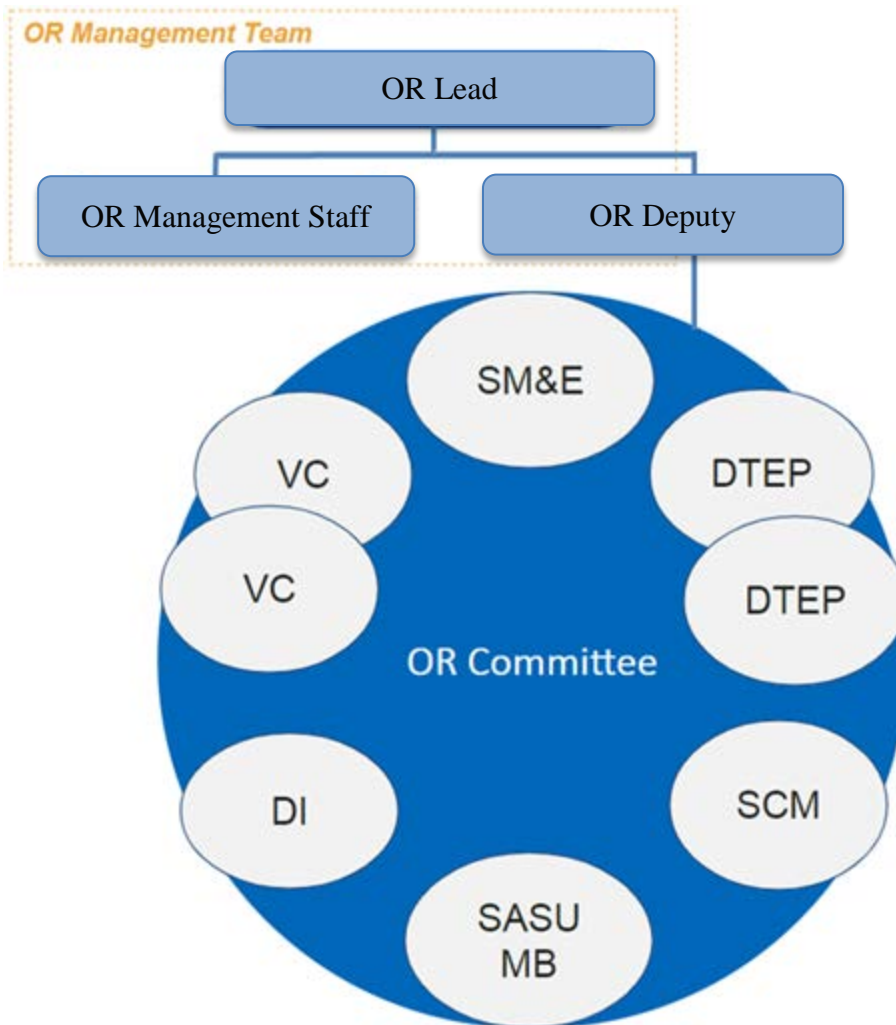
Responsibilities of the **OR Management Team** include:

- Coordinate with the PMI Senior Management Team on OR priorities
- Manage OR communications to PMI HQ and Country teams
- Manage CNs, track proposals/protocols/reports, and budgets

Key responsibilities of the **OR committee** includes:

- Include at least one person from each technical team on the committee
- Coordinate with technical teams to develop top list of OR priority ideas to present to PMI senior management team yearly
- Coordinate with technical teams to support development of scientifically strong concept notes, protocols, and budgets
- Report out on OR priorities, results, and developments to PMI's internal and external stakeholders
- Oversee appropriate dissemination of findings and their decision implications
- No longer approve/reject OR concept notes





## Reclassification of OR Study into an Assessment

PMI funds should not be used to change a study that has been rejected by the OR Committee into an assessment (i.e., no longer labeling the activity as OR) unless there is a clear statement in the approval form recommending such an action or the study is given a non-OR determination by the Committee based on the operational research definition outlined in the *PMI Strategy 2015-2020*.

## Research Determination Process

Research determination is the systematic evaluation of whether a proposed activity constitutes research and involves human subjects, and it is best done by an independent unit. Given CDC and USAID's partnership in PMI, effort needed to marry two different approaches to research.

- As an HHS agency, CDC conducts research with a wide array of partners (e.g., NIH, academic institutions, etc.) and leverages the Office of Human Research Protections (OHRP) for oversight and support.
- USAID, as a foreign assistance development agency, directly conducts monitoring and evaluation of its programs by USAID staff, but does not use its staff to directly conduct research; instead relies on implementing partners with proper approvals. USAID supports hundreds of millions of dollars in basic and applied research each year in collaboration with implementing partners.

CDC has a Federal-wide Assurance (FWA) and Institutional Review Board (IRB) for its extensive portfolio of research whereas USAID does not (as USAID relies on IRBs of the research institutions or partner entities directly implementing the research). All CDC activities must be reviewed to determine whether they are research involving human participants. In this context, “Involving human subjects” means obtaining information about living individuals. There is an ethical and legal obligation to ensure that individuals are protected in all public health research activities. PMI upholds this obligation no matter what partner conducts PMI-supported OR.

## Facility Surveys and Blood Collection in the Context of OR

PMI supports periodic health facility surveys for a variety of reasons, most often to assess the current status and quality of service delivery and to inform improvement activities. Survey designs that follow standard health facility survey practices (observations, exit interviews, record reviews, slide re-checking, etc.) are not considered OR. However, the addition of secondary blood collection for confirmatory diagnostic testing or molecular investigation is NOT considered standard. Methodologies involving blood sample collection as part of a facility survey are subjected to the OR process.

PMI-supported analysis of blood samples collected with external support (i.e., PEPFAR surveys, non-PMI funded studies) may also qualify as OR and be subjected to the OR process. Please consult with the OR committee for a determination of whether the proposed PMI-supported analysis is OR or considered to be a monitoring activity.

## Reporting Requirements for Ongoing OR Activities

PMI-funded OR 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 January-June will be due in July; a report covering activities July-December will be due in January. A template to guide preparation of the progress report can be found in **OR Appendix 2**. Information submitted on progress reports will be used to monitor study implementation, coordinate among studies, and for internal or external updates including the IAG and PMI annual report. A completed study questionnaire, final report,

and/or data presentation is required at study completion. **Conference abstracts and manuscript drafts resulting from the study must also be submitted for clearance through PMI HQ prior to submission (see Section A for additional guidance on clearance) AND as final versions to the OR Management Team upon acceptance.** Please note that submission of abstracts and manuscripts to the OR Coordinator is not for review but for notification purposes only.

## Authorship Publications Resulting from OR Activities

PMI encourages 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 activities. A widely accepted International Committee of Medical Journal Editors guidance on defining roles of authors and contributors is available online: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>.

Prior to preparing manuscripts and abstracts for submission to scientific peer-reviewed journals and conferences, authors should consider reviewing and adopting the reporting guidelines developed for different study designs such as:

- CONSORT for randomized trials ([www.consort-statement.org](http://www.consort-statement.org))
- Clinical Trials (<https://clinicaltrials.gov/>)
- STROBE for observational studies (<http://strobe-statement.org/>)
- STROME-ID extension of STROBE for Reporting of Molecular Epidemiology for Infectious Diseases ([http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(13\)70324-4/abstract](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(13)70324-4/abstract))
- PRISMA for systematic reviews and meta-analyses (<http://prisma-statement.org/>)
- PRISMA-P for systematic reviews and meta-analyses protocols (<http://www.prisma-statement.org/Extensions/Protocols.aspx>)
- STARD for studies of diagnostic accuracy ([www.stard-statement.org/](http://www.stard-statement.org/)).
- SRQR Standards for reporting qualitative research: a synthesis of recommendations (<http://www.ncbi.nlm.nih.gov/pubmed/24979285>)
- CHEERS Consolidated Health Economic Evaluation Reporting Standard Statement (<http://www.ispor.org/Health-Economic-Evaluation-Publication-CHEERS-Guidelines.asp>)
- Reporting guidelines for implementation and operational research (<http://www.who.int/bulletin/volumes/94/1/15-167585/en/>)
- Gather for studies that calculate health estimates (<http://gather-statement.org/gather-statement/>)

## **Guidelines for Listing PMI and Agency Affiliations for OR Activities**

Please refer to **PMI Policy**.

## **OR Appendix 1: PMI OR Study Concept Note- Submission Template (for MOP or core-funded OR)**

Study title:

Point of contact (specify both PMI POC and project PI, if different): Country (-ies):

Program area(s) (e.g., ITNs, Case Management, MIP, IRS, etc.): Interagency technical team(s) consulted (Core-funded OR only): Type of study:

Total Study Budget:

Annual study budget by FY (if funded from multiple FY):

Source of study funds (e.g., Core, MOP including reprogrammed MOP funds): Study start and end dates (anticipated):

Mechanism and partners (clearly indicate prime partner and local partners if applicable, including NMCP):

Concept note should be 2-4 pages in length, not including header material and budget justification. Be as clear and explicit as possible in each of the sections. Information that must be included is described below. If the requested information is not included in the concept note it will be returned for completion before OR Committee review.

### **Project Background:**

- What is the main research objective(s)? Clearly state what the study will examine and its anticipated outcomes.
- How will the anticipated study outcomes impact NMCP programs, national policy or operational issues and/or PMI strategic efforts at large?
- Please describe briefly any other studies (current, planned, or recently completed) addressing similar questions in the same or different locations. A list of PMI-funded Operational Research studies is available at [www.pmi.gov](http://www.pmi.gov). If other similar studies are being done, what added value will come from the proposed study?

### **Research Methods:**

- Clearly and concisely describe the study methods, including the parameters below where applicable:
  - Study area
  - Study Population
  - Human subjects clearance process/ethical clearance (specify institution(s)) Study design
  - Sample size (must be sufficient to achieve study objectives) Subject and control recruitment
  - Interview data collection
  - Biological sample collection and tests Statistical analysis
  - Timeline

- Describe how data and results of the research will be disseminated to relevant in-country partners (e.g., NMCPs) to ensure that outcomes are known on a timely basis.

**Budget Justification:** Explain the study costs including overhead charges using the table provided below.

**PMI Operational Research Project Budget Justification**

<u>Item</u>	<u>Cost (USD)</u>
<i>Personnel</i>	
<i>Supplies</i>  <i>NOTE: include a separate budget line for items to be procured through the supply chain mechanism</i>	
<i>Equipment</i>	
<i>Training</i>	
<i>Travel</i>	

<u>Result dissemination/outreach</u>	
<u>Overhead</u>	
<u>Other costs</u>	
<b>Total</b>	

## **OR Appendix 2: PMI OR Semi-Annual Progress Report Template**

Title:

Country (if multiple please list):

Research Institution and/or non-USG collaborators (if applicable): PI name and email address:

PMI POC name and email address:

Study start date (mm/yyyy):

Study end date (actual or expected – mm/yyyy): PMI budget amount:

Funding source(s) (Core and/or MOP): Fiscal year(s) of funds:

Funding mechanism:

Program area (e.g., Case Management, LLINs, IRS, MIP, SBC, Pre-Elimination/ Transmission Reduction, HSS, and/or SM&E):

Summary (2-4 sentences summarizing the study objectives):

Status (CN approved, Protocol approved, Ongoing, Completed, or Published): If study has not started, explain why:

Progress in the past six months (July 2016-December 2016) and results to date (2-4 paragraphs, include preliminary data and figures where possible):

Conclusions/major outcomes:

Program or other impact:

Publication status and citation(s) if relevant:



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# COMMODITY PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

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

PMI will procure PBO ITNs in specific settings. Please see the **ITN** chapter for more details.

PMI will procure new dual insecticide nets and can access a co-payment under Unitaids' and Global Fund's New Nets Project. Please see the **ITN** chapter for more details.

PMI is requiring greater standardization of the pyrethroid ITNs in terms of size, shape, color, material, accessories, and package artwork.

PMI will no longer allow sole source procurement of RDTs.

PMI recommends that countries in sub-Saharan Africa procure RDTs that test for *P. falciparum* only with the exception of Ethiopia and Madagascar, where *P. vivax* is common.

Direct warehousing and distribution costs should be included as a separate line item in the MOP from both the commodity and the technical assistance activities. The EUV costs should be included as a separate line in the MOP.

**PMI supports GS1 standardization across the supply chain.** PMI is requiring, in a phased approach, that its vendors include GS1 barcodes on products it procures. Country teams should consider supporting country regulatory authorities to require GS1 standards to eventually improve track and trace capabilities. PMI also supports technical assistance to countries interested in implementing GS1.

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# COMMODITY PROCUREMENT

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## Introduction

Under the PMI strategy, one of the five key areas to achieve our objectives is the continued scale up of proven interventions, all of which are predicated on the availability, in one way or another, of high quality commodities. In addition, FY 2020 holds the promise of a number of new malaria control tools including next generation ITNs, tafenoquine, and new G6PD diagnostics. Careful planning for introduction and monitoring of deployment for next generation ITNs is required. Any introduction of tafenoquine and new G6PD diagnostics would be in an OR setting. Please refer to the **Case Management** chapter for further updates on these two new tools.

Prior to MOP visits, country teams should work with their NMCPs and partners to update national-level gap analyses – typically using information from stakeholder-coordinated forecasting and supply planning efforts and/or Global Fund concept notes – for all key malaria commodities in order to have a thorough understanding of the priority commodity needs looking forward. In the estimated commodities costing sheet, found at the end of this chapter, the cost of commodities includes the costs of goods plus estimates on freight, insurance to port, clearance costs, and required quality assurance testing. Note that the reference price used by Global Fund is based on the commodity cost only. Country teams should also take into account the difference in planning requirements for warehousing and distribution needs of the various commodities when preparing order requests and build in the additional funding to the appropriate partner if needed. Countries should be aware of product lead times, which include production, quality assurance testing, shipping and customs clearance; the procurement of many malaria commodities require a lead time of eight months to more than a year. (Refer to **Commodity Procurement and Supply Chain Management Appendix 1** for product and country specific lead times).

## Types of Commodities

Commodities procured by PMI include: ITNs, ACTs, SP (for IPTp) and AQ+SP (for seasonal malaria chemoprevention), drugs for severe malaria, other malaria pharmaceuticals (e.g., chloroquine, primaquine, and quinine tablets), laboratory equipment, microscopes and supplies for microscopy, RDTs, insecticides for IRS, spray equipment, and related personal protective gear. For IRS-specific commodities, please refer to the **IRS** chapter, as this chapter will not address IRS commodities. Additionally, most commodities necessary to implement national surveys (e.g., Malaria Indicator Survey) do not fall within the scope of PMI's malaria commodity procurement partner and alternative arrangements should be made. Please contact the GHSC-PSM TO2 COR as soon as possible when discussions around the procurement of these malaria-related commodities for national surveys begin (Linda Gutierrez: [lgutierrez@usaid.gov](mailto:lgutierrez@usaid.gov)). Please also consult the **SM&E** chapter for greater detail around the

procurement of those commodities (particularly RDTs and ACTs). As with all procurements, lead times can be lengthy so any research or studies that require commodities should plan sufficiently in advance (see **Commodity Procurement and Supply Chain Appendix 1**).

### *Insecticide-treated nets*

Currently, PMI procures nets with WHO Prequalification for Vector Control Products listing. Currently, there are 19 approved ITNs. This list includes five PBO ITNs, the Interceptor G2 net, a next generation net that includes chlorfenapyr in addition to a pyrethroid and Royal Guard, a next generation net that includes piraproxifin in addition to a pyrethroid.

The PBO nets have a WHO policy recommendation (September 2017) that now makes them eligible for PMI procurement. The ITN chapter of this guidance outlines PMI's approach to implementing the policy, including the criteria to meet in order to make them eligible to procure. Most PBO nets cost between \$2.75 and \$3.00, around \$1.00 more per net than a standard pyrethroid-only net.

The Interceptor G2 ITN does not have a WHO policy recommendation, however, PMI is joining Unitaid and the Global Fund in supporting a catalytic initiative that provides a co-payment mechanism to bring the cost of next generation nets close to the cost of a standard pyrethroid net and support evidence generation on the effectiveness of the next generation nets. Next generation nets, specifically the Interceptor G2, will be eligible for procurement under this initiative and for approved operations research. Further guidance on deployment of next generation nets, including the criteria that must be met, is provided in the ITN chapter.

For technical and programmatic reasons, PMI does not procure ITNs approved through the WHOPES equivalency program (i.e., "me-too" nets) or converted to WHO PQ, as "me-too" nets have only passed phase I (laboratory-based) testing and the "me-too" determination is only based on chemical equivalency to the innovator net. Please refer to details regarding the decision to deviate from WHOPES found on [pmi.gov](http://pmi.gov) [http://pmi.gov/docs/default-source/default-document-library/tools-curricula/itn\\_procurement\\_specifications.pdf?sfvrsn=4](http://pmi.gov/docs/default-source/default-document-library/tools-curricula/itn_procurement_specifications.pdf?sfvrsn=4).

PMI had procured over 20 different types of ITNs across dimensions, shape, color, and material. The variation has been driven, in part, by net user preferences. However, a PMI-funded analysis demonstrates that while net users do have preferences, these preferences do not impact use.<sup>155</sup> The analysis showed that the biggest factor in use was that a net was provided, not that it met user preferences. With this analysis, the supply chain team worked to identify opportunities to rationalize ITN procurement to achieve best value. The Supply Chain team reviewed the ITN market including conducting an ITN cost of goods analysis, discussed the market and

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<sup>155</sup> Koenker, H. and Yukich, J.O. Effect of user preferences on ITN use: a review of literature and data. *Malaria Journal* 16:233 (2017) (<http://rdcu.be/tal2>; accessed, August 2017)

procurement approaches with other global ITN procurers (Global Fund and UNICEF), and conducted a survey of ITN manufactures.

The landscape analysis highlighted that while ITN prices have dropped significantly over time, there were additional lead time and cost savings that could be gained through greater standardization. Additionally, standardization would lead to greater interchangeability allowing flexibility in moving nets across orders/countries to meet unanticipated demand, and smoothing out production for manufacturers, which also leads to cost and time savings. The need to demonstrate greater efficiencies and value for money is even more important in the current funding environment and with the need to secure the additional resources to deploy more costly, new generation ITNs to combat growing pyrethroid resistance.

The standards for PMI procured pyrethroid ITNs effective beginning with FY 2018 MOP orders are:

1. Standardize shape to rectangular
2. Standardize ITN height to two heights: 150 cm and 170 cm
3. Standardize ITN color to white (no other colors)
4. Do not include hooks and nails in ITN package
5. Do not restrict competition based on material
6. Limit packaging artwork to PMI logo, standard language (e.g., not for retail sale) and pictorial instructions

If a country needs to deviate from these standard specifications for regulatory reasons, they must justify the additional cost in consultation with the PMI Headquarters Supply Chain and ITN Teams and be granted an exceptional approval from PMI Agency Leads.

PMI requires that all ITNs procured for routine 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 matter of hours. However, if a bale were to be opened in a routine 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, rats, or moisture than individually packaged nets. Furthermore, if the ITN is distributed at a central point, like a health center or school; and then transported some distance to individual homes, there is a risk that the ITN might be damaged before it is hung. For this reason, programs should procure ITNs using individual bags for use in continuous or routine distribution. If a country feels they have a reason to procure ITNs in bulk packaging for a distribution system other than campaign, a justification must be submitted with the order request.

There are ongoing durability studies which may impact procurement policy in the future (see the **ITN** chapter for information on ITN durability). Lisa Hare ([lhare@usaid.gov](mailto:lhare@usaid.gov)) or Lilia Gerberg ([lgerberg@usaid.gov](mailto:lgerberg@usaid.gov)) should be contacted for more information on ITN procurement policy, and

John Gimnig (hzg1@cdc.gov) and Jen Armistead (jarmistead@usaid.gov) regarding the insecticide residual longevity component of ITN testing.

ITN campaigns often require very early planning, ordering, delivery, and significantly greater net quantities, all of which must be considered in order for the timely arrival of nets and for manufacturers to be able to meet production demand. In contrast, continuous ITN distribution often requires planning for more regularly spaced orders, adequate permanent warehousing options, and more consistent net quantities. **Regardless of the distribution mechanism(s), ITN lead times are approximately ten months, and must be accounted for during planning processes (see Commodity Procurement and Supply Chain Appendix 1).**

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

While PMI prioritizes the procurement of a country's first-line drug, if necessary, PMI-financed alternate first-line or second-line therapies is allowable. With the introduction of SMC in several PMI countries, a number of countries switched to two first-line ACTs (adding AL for the lower weight bands). Exceptions to this policy require approval from Agency Leads. Although PMI procures a range of antimalarial drugs, consistent with WHO malaria treatment and prevention guidelines (as well as aligned with IMCI guidelines under PMI's iCCM rubric), PMI does not procure ACTs without *either* an approval through a stringent regulatory authority (SRA)<sup>156</sup> (such as the US FDA) or the WHO PQ Program.<sup>157</sup> Stringent regulatory authorities employ a robust drug dossier review to consider the safety, efficacy, and quality of pharmaceuticals intended for human use.<sup>158</sup> Although several SRA-approved ACTs have come to market in the last 10 to 15 years, PMI has expanded its procurement to include WHO PQ ACTs to ensure sufficient supply to meet demand. While the WHO is not a regulatory body, their PQ for artemisinin-based and other products indicated in the treatment of malaria applies a robust dossier and manufacturing site review process, resulting in approved products of known quality, safety, and efficacy.<sup>159</sup>

Currently, there are three ACT products approved by a stringent regulatory authority, two of which have been procured with PMI funding: Novartis' Coartem<sup>®</sup> (artemether-lumefantrine), Alfasigma's Eurartesim<sup>®</sup> (dihydroartemisinin-piperaquine), and Shin Poong's Pyramax<sup>®</sup>

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<sup>156</sup> Currently, the drug regulatory authorities of the European Union, Japan, USA, Canada and Switzerland have implemented International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and are considered stringent regulatory authorities. There are also various industry organizations from the aforementioned countries who hold SRA status, and some member states with observer status. For more information, visit <http://www.ich.org/about/membership.html>

<sup>157</sup> <http://apps.who.int/prequal/query/ProductRegistry.aspx>

<sup>158</sup> The ICH is an internationally recognized body comprised of representatives from regulatory agencies and pharmaceutical companies globally to help develop standards around drug registration with an objective to harmonize interpretation and application of technical guidelines.

<sup>159</sup> Historically, the WHO PQ approved only ACTs antimalarials (co-blistered products and now co-formulated). Recently, however, non-ACTs used in SMC have been approved through the prequalification program.

(pryonalidone/artesunate).<sup>160</sup> There are also several fixed-dose combination ACT formulations with approval through the WHO PQ. The PQ approval process operates on a rolling basis, which means new products are approved periodically. Several fixed-dose combination formulations of both artemether-lumefantrine and artesunate-amodiaquine have been approved by WHO PQ and therefore added to the WHO prequalification list<sup>161</sup> over the recent years. PMI can procure these products and subjects them to the same testing requirements of other non-SRA approved pharmaceuticals procured with PMI funds.

Since 2015, there have been a number of new fixed-dose combination formulations of artemether-lumefantrine approved through the WHO PQ. Specifically, there are now several different co-blister oral presentations: 80 mg artemether/480 mg lumefantrine, 60 mg artemether/360 mg lumefantrine, and 40 mg artemether/240 mg lumefantrine. These new presentations are intended to improve compliance relative to the previous 20 mg/120 mg presentation, which placed a relatively heavy pill burden on the recipient. Unlike the older historical 20/120 tablet presentations, these newer formulations do not allow for weight band substitution. Like any newly procured pharmaceutical, please take into consideration the registration status and the potential need for an importation waiver if the product is not registered.

PMI policy to procure either SRA-approved or WHO-prequalified ACTs is one element of ensuring quality of pharmaceutical products procured with PMI funds. Despite this, ensuring good quality non-ACTs and other essential medicines, continues to be challenging. For example, PMI sources quinine from pre-approved wholesalers.<sup>162</sup> The wholesaler agencies are routinely evaluated against internationally accepted quality assurance standards by a USAID-led team, comprised of USAID in-house pharmacists, QA implementing partners, and consultants with significant experience in both current good manufacturing practices and US FDA practices. Wholesalers are required to employ strict QA/QC measures with their vendors. Re-evaluation with site visits and desk audits is routinely carried out. Product testing is conducted at qualified laboratories; ISO-17025 compliance and/or a WHO prequalification are acceptable facilities.

**Historically, average lead times for ACTs have been about seven to nine months from time of receipt of a completed requisition order form** (and average lead times for other anti-malarials and essential medicines are about ten to fourteen months). Please see the lead time table in **Commodity Procurement and Supply Chain Appendix 2**.

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<sup>160</sup> PMI has yet to receive a request from any PMI focus country to procure Pyramax.

<sup>161</sup> <http://apps.who.int/prequal/query/ProductRegistry.aspx>

<sup>162</sup> Please see most recent ADS 312 for more information on currently approved wholesalers.

## *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 has been no WHO PQ or SRA approved options for SP indicated for use in IPTp;<sup>163</sup> as such, PMI has sourced SP from pre-approved wholesalers.<sup>164</sup> However, there are currently dossiers under review by the WHO PQ for monotherapy SP intended for use in pregnant women as part of IPTp, although it is unclear when/if either of these products will receive prequalification.

**Historically, SP lead times have been lengthy, around 10-11 months from date of receipt of completed requisition order form to delivery in country.** Confounding already long lead times are issues around lack of registered product in the presentations required by PMI-supported countries and acquiring the appropriate importation waivers. As country teams quantify national level SP needs during operational planning visits for IPTp and SMC, consideration must be given regarding lengthy lead times.

## *AQ+SP for seasonal malaria chemoprevention*

Since the 2012 WHO policy recommendation regarding SMC, several PMI countries in the Sahel have begun implementing SMC programs. The SMC intervention entails the administration of up to a maximum of four consecutive monthly rounds of amodiaquine and sulfadoxine-pyrimethamine (AQ+SP co-blister or loose AQ and SP) to children ages 3 months to 59 months in the Sahel region. PMI will be implementing SMC in up to nine countries in 2019 and can procure AQ+SP for use in SMC campaigns. Currently, there is only one manufacturer producing WHO prequalified co-blister presentations of AQ+SP (i.e., packaged in a blister pack together for ease of use), in both dispersible and non-dispersible formulations. Historically, the limited production capacity has led to challenges in implementing SMC in PMI-supported countries. For countries implementing SMC, please note that there is a section in the MOP template including commodity gap tables for AQ+SP.

Given the time-sensitive nature of SMC campaigns (i.e., administration of SMC medicines takes place only during the rainy season and peak malaria transmission), commodity procurements must take place well in advance, taking into account lengthy lead times of these medicines and the need to pre-position commodities where they are geographically needed. The PMI Headquarters 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

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<sup>163</sup> SP is included in two co-blistered presentations currently approved through the WHO PQ. However, neither of those presentations is indicated for use in IPTp.

<sup>164</sup> Please see most recent ADS 312 for more information on currently approved wholesalers.

product.<sup>165</sup> **If SMC is relevant to your country team and PMI is requested to procure commodities, orders must be firmly placed at least one year in advance of planned campaign dates to ensure availability of the needed drugs in advance of the campaign.** Please contact Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)) or Alexis Leonard ([aleonard@usaid.gov](mailto:aleonard@usaid.gov)) for questions.

### *Severe malaria medicines*

Lead times for all preparations of medicines indicated in the management of severe malaria are lengthy and should be taken into consideration by country teams during quantification. PMI is able to procure any of the three available WHO prequalified injectable artesunate presentations (30-, 60- and/or 120-mg formulations). There are also three different strengths of rectal artesunate suppository presentations available (50-, 100- and/or 200-mg formulations), although only the 100-mg preparation has approval through the WHO prequalification program (through two separate vendors). WHO recommends the use of the 100-mg rectal artesunate suppositories. Currently, PMI does not mandate one presentation over the other but notes WHO's recommendation of the 100-mg presentation, given the potential for subtherapeutic dosing with the 50-mg presentation as well as the lack of prequalified products. Please see the **Case Management** chapter for additional information. Injectable artemether and quinine are also available for procurement, although neither has approval through the WHO PQ. Please see the **Case Management** chapter for further information on the appropriate selection of injectables. While auxiliary medicines used in the management of severe malaria are also available for procurement (e.g., glucose/normal saline for intravenous use, paracetamol, etc.), few will have approval from a stringent regulatory authority, and there may be potential issues around registration. 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, please see **Appendix 3** and contact Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)) or Meera Venkatesan ([mvenkatesan@usaid.gov](mailto:mvenkatesan@usaid.gov)).

### *Rapid diagnostic tests*

To help countries select RDTs appropriate for use given country-specific epidemiology, WHO, FIND, and CDC have conducted seven complete rounds of standardized product testing of commercially-available RDT kits, submitted voluntarily by manufacturers. Through this testing, 147 products have been evaluated for accuracy in detecting standardized whole blood samples of *P. falciparum* and *P. vivax* (for tests designed to detect multiple species). Products also underwent assessment for heat and humidity stability. These assessments identified a number of RDTs that performed well at parasite densities of 200 parasites/microliter; some tests, however, did not perform as well. A summary of results from rounds 1–8 of malaria RDT product testing

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<sup>165</sup> There are several dossiers for additional SP/AQ products currently under review by the WHO Prequalification Program, including two for dispersible formulations (one of which also has ERP approval through the Global Fund).



can be found here: <https://apps.who.int/iris/bitstream/handle/10665/276193/9789241514958-eng.pdf?ua=1>.

Building on the results of eight rounds of product testing completed to date, WHO, in collaboration with PMI and other development partners, has developed an information note on recommended selection criteria for procurement of malaria rapid diagnostic tests. Of those products submitted and tested to date, the note lists all RDTs that meet quality standards and are, therefore, recommended by WHO for procurement. At the time of publication of this document, the most recent WHO procurement selection note can be found here (revised in March 2016): <http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf?ua=1>. In 2018, product testing was integrated into WHO's diagnostic pre-qualification program. Currently, products from three of PMI's RDT suppliers are pre-qualified. As of December 2017, WHO determined that there are sufficient numbers of the HRP-2 *P. falciparum* RDT prequalified. Therefore, it recommends that only WHO PQ *P. falciparum* RDTs should be procured. There is an insufficient number of WHO PQ RDTs for the combo and pan RDTs, so WHO recommends that procurers continue to use FIND/WHO product testing results for combo and pan tests. PMI is reviewing the list of HRP-2 *P. falciparum* RDTs that have received WHO PQ with the list of *P. falciparum* RDTs that have passed PMI's quality review and determined we now require WHO PQ for *P. falciparum* RDTs.

Two criteria must be met in order for PMI to procure an RDT for any given country:

1. The RDT is appropriate to the country's detection settings and epidemiology. (PMI recommends that countries in sub-Saharan Africa procure RDTs that test for *P. falciparum* only with the exception of Ethiopia and Madagascar where *P. vivax* is common; see the **Case Management** chapter for a more detailed explanation).
2. The product is on the WHO RDT procurement selection note or has received WHO pre-qualification.

A recent analysis of procurement data has shown that prices for RDTs that are sole-sourced are up to twice the price of the same RDT when there is open competition. An additional analysis undertaken by MalariaCare found that all countries either were using multiple brands of RDTs concurrently or had switched brands. Health workers were able to manage multiple RDT brands or switching brands without significant issues in use. Supervision and job aids supported health workers in managing the change. As such, **PMI no longer allows sole source selection of RDTs based solely on health worker training concerns beginning with FY 2018 MOP orders.** The Case Management team will help countries work through the implications of this new policy including supporting the development of training and job aids focused on managing different RDTs rather than a single RDT.

WHO has identified malaria parasites with HRP-2 deletions in limited areas of sub-Saharan Africa (see **Case Management** chapter for more details). In settings where HRP-2 deletions are

sufficiently prevalent, HRP-2 RDTs may no longer be accurate, and RDTs using non-HRP-2 antigens may be needed. Single-species tests that detect two *P. falciparum* antigens (HRP2 and pLDH) with two test lines are now available. These tests are difficult to interpret in the case of conflicting results and do not generally provide a diagnostic advantage in detecting symptomatic malaria. **Given the challenges in interpretation and the limited settings experiencing prevalent HRP2 deletions, PMI will not procure two line multi-antigen RDTs for *P. falciparum*.** Some manufacturers also produce a single line RDT that contains antibodies to both HRP-2 and pLDH. It is hoped that this type of test might be a programmatic solution in countries with HRP-2 deleted parasites in limited areas. These tests, though, have not yet been validated against HRP-2 deleted parasites (although WHO is pursuing this validation) and, therefore, cannot at this time be recommended for use in areas where HRP-2 deletions have been identified. **Countries that either have evidence of HRP-2 deleted parasites or that suspect that such deleted parasites exist in their countries should contact the PMI Case Management Team for guidance on methods to document the presence of these parasites and for recommendations on alternative RDTs if such deletions are detected. Please also refer to WHO guidance** (<http://apps.who.int/iris/bitstream/10665/258972/1/WHO-HTM-GMP-2017.18-eng.pdf>).

RDTs that test for glucose-6-phosphate dehydrogenase (G6PD) deficiency have recently been developed by a couple of manufacturers, but have not yet received a recommendation from WHO. A PMI-supported field test of one brand of this RDT (CareStart®) demonstrated that they can detect major G6PD deficiencies, but can miss some minor deficiencies. There are several more sensitive G6PD tests under development, most of which require a device (i.e., not an RDT) and are estimated to be available in 2019. As G6PD testing is not required prior to administration of low-dose primaquine for radical cure of *P. falciparum*, such testing is only indicated prior to radical cure treatment for *P. vivax*. Therefore, requests for procurement of G6PD tests will be considered on a case by case basis only from PMI countries with ongoing *P. vivax* transmission. If relevant in your country programs, please contact the PMI Headquarters Supply Chain and Case Management Teams to discuss the planned indications and deployment of these G6PD RDTs.

Please contact Alexis Leonard ([aleonard@usaid.gov](mailto:aleonard@usaid.gov)) or Lisa Hare ([lhare@usaid.gov](mailto:lhare@usaid.gov)) for questions around RDT procurement; for queries around technical assistance, contact BK Kapella ([bkapella@cdc.gov](mailto:bkapella@cdc.gov)), Meera Venkatesan ([mvenkatesan@usaid.gov](mailto:mvenkatesan@usaid.gov)), and Larry Barat ([lbarat@usaid.gov](mailto:lbarat@usaid.gov)).

### *Lab supplies*

Lab supplies (microscopes, reagents, slides, additional parts etc.) are rather specific and can require significant time to procure; please plan orders accordingly. For information on procuring entomological supplies, see the **Entomological Monitoring** chapter.

## Lot Quality Assurance/Quality Control

Quality, safety, and efficacy issues continue to be a concern and, therefore, a continued priority in the procurement of all malaria pharmaceuticals, RDTs, and ITNs. All pharmaceuticals approved by non-SRAs, including those approved through the WHO PQ, must be tested prior or concurrent to shipment (depending on how they were approved and on historical volumes procured) in accordance with PMI standard operating procedures and work instructions (detailed documents developed by PMI's QA partner). For all pharmaceuticals, there is a quality testing strategy, with WHO-prequalified and wholesaler-sourced products requiring compendial testing. For the latter group, the timing of testing – either pre-shipment or concurrent – is dependent upon time from PMI procurement of a newly qualified product or batch quantity testing. Additionally, while routine testing of SRA-approved products is not necessary, PMI's QA strategy includes an annual sampling of retain samples for all SRA-approved products, based on volumes procured, which includes compendial testing.

Historically, RDTs have been subjected to 100% quality control lot testing at WHO-supported laboratories to ensure appropriate test performance and long-term stability. PMI is now implementing a risk-based strategy based on volumes procured (with related QC compliance), and WHO prequalification status. Additionally, there will likely be a transition in early 2020 regarding laboratory testing facilities, although this is not expected to have a significant impact on RDT deliveries, etc. Once the new arrangements are finalized, updated guidance will be circulated.

ITNs undergo a physical inspection at the manufacturing site to identify any defects prior to release for shipping. Additional mechanical and chemical testing based on WHOPES standards is undertaken on samples and at qualified testing facilities concurrent to shipping. PMI has worked with the Global Fund and UNICEF to harmonize pre-shipment inspection and testing protocols for ITNs.

All test reports (of pharmaceutical, RDT, and ITN quality) are kept on file electronically with PMI's quality assurance partner and with the PMI Headquarters Supply Chain Team. These may be obtained upon request by PMI country teams and regional advisors. If there are requests from external parties for specific quality control test results, please contact PMI's in-house clinical pharmacist, Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)), as these data are considered sensitive.

Products will not be released for delivery until results are received by the QA/QC team and deemed as passing (i.e., in compliance with industry and internationally accepted QA/QC standards).

## Emergency Commodity and Financial Accounts

Country teams, with the assistance of supply chain/pharmaceutical management implementing partners, are requested to monitor the availability of all key malaria commodities (i.e., ACTs, SP, RDTs, ITNs, and related drugs and supplies for severe malaria) procured and distributed in country, regardless of donor, and take action when disruptions in supply are likely. Fluctuations in donor funding, commodities availability, and resulting stock outs have been a recurrent problem for country programs and may continue with potential decreases in donor contributions. PMI has observed that transition to a new Global Fund grant has posed supply risk in the past. 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 holds an emergency commodity funding account that can be utilized by countries to help avert stockouts of ACTs, RDTs, and severe malaria drugs, and maintain flexibility in commodity funding.<sup>166</sup> Additionally, PMI has developed an ACT stockpile, which holds a relatively small cache of buffer stock, including all four original weight bands for Coartem<sup>®</sup> (artemether/lumefantrine)<sup>167</sup>. Countries may access this buffer stock to help mitigate pending ACT stockouts, albeit quantities are relatively limited so large-scale emergency procurements are not possible. Because of the relatively short shelf life of most ACTs (24 months), the stockpile stock can often fall under countries' importation shelf life requirements of 75 to 80 percent remaining shelf-life. As the stockpile stock is typically drawn on when countries are facing stock shortages and the amounts provided are typically only 1 to 2 months of stock, countries can accept lower shelf life product without risk of expiry. For example, if a country is experiencing a stock out and is provided with a 2 month supply stockpile stock with 50% shelf life (12 months remaining shelf life), this stock will be used before it expires in a year. As such, country teams are encouraged to work with NMCPs and drug regulatory authorities to seek waivers for the importation of lower shelf-life product 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. Linda Gutierrez ([lgutierrez@usaid.gov](mailto:lgutierrez@usaid.gov)) should be contacted for further information on utilizing the Emergency Commodity Account and/or the ACT buffer stockpile.

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<sup>166</sup> Given the typical quantities of LLINs, long lead times, method of transportation and sheer physical bulk (necessitating shipment by sea only), the emergency commodity funds are only used rarely for the procurement of LLINs.

<sup>167</sup> PMI no longer holds an AS/AQ emergency stockpile, but the Supply Chain Team will work with its implementing partner to address any urgent needs of AS/AQ.

## Commodity Theft, Diversion, and Expiry

PMI implements stringent methods to try and ensure that all malaria commodities procured arrive to the intended country and user. However, malaria commodities, especially ACTs, are considered of high street value and most have relatively shorter shelf lives compared to other pharmaceuticals. Although PMI is ever vigilant to combat and avoid all forms of theft, diversion, and expiry of our malaria commodities, these issues can still occur. If your country is aware of, suspects, or hears of any form of loss of malaria commodities whether through theft, diversion, or destruction (e.g., fire), it is crucial to immediately report the incident to the USAID Office of the Inspector General and to USAID/Headquarters (including the PMI USAID Agency Lead) and the PMI Headquarters Supply Chain Team (listed below) with any information such as photos, lot numbers, location where the loss took place, etc. PMI is required to report to the Inspector General any type of loss or theft. In addition, it is crucial to understand any potential issues for our programs in country. Such issues require immediate attention as they indicate that there may be a broader systemic issue in the country, represent a loss of U.S. tax dollars, and mean fewer people are protected from and treated for malaria. Countries should identify options to mitigate the risk of theft, including regular inspection of storage facilities, review of inventory records, and comparison of logistics and case management data to identify significant discrepancies between reported cases and consumption. Countries should also work to strengthen the national regulatory authority.

With regards to expiry, PMI and its procurement agent, manufacturers, and wholesalers aim to deliver medicines into country with the maximum shelf life possible. At times, delays with manufacturers and/or freight forwarders, combined with poor infrastructure in country and a lack of prepared distribution plans, collectively can lead to commodities arriving with shorter than preferred shelf-life. Because most countries also have a minimum required shelf-life for pharmaceuticals and related medical commodities, they may reject product on this basis. All methods to avoid expiry of any malaria pharmaceuticals should be tried before allowing expiry. PMI should be informed well in advance if there is potential for expiration, as USAID/Washington may be able to find ways to support emergency re-distribution to areas that could use the needed commodities. If expiry does occur, PMI should be immediately informed and a report will need to be documented for the record regarding the expiry as expiry of US-donated commodities falls under waste/fraud/abuse statutes.

PMI Headquarters Supply Chain Team Contacts: Linda Gutierrez ([ligutierrez@usaid.gov](mailto:ligutierrez@usaid.gov)), Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)), Alexis Leonard ([aleonard@usaid.gov](mailto:aleonard@usaid.gov)), Christie Hershey ([chershey@usaid.gov](mailto:chershey@usaid.gov)), Lisa Hare ([lhare@usaid.gov](mailto:lhare@usaid.gov)), Clerisse Lemke ([clemke@usaid.gov](mailto:clemke@usaid.gov)) and Chris Warren ([jwarren@usaid.gov](mailto:jwarren@usaid.gov)).

## Central Commodity Mechanisms

While PMI has two central procurement options available to Missions for procurement of non-IRS commodities, the central procurement and supply chain management agent (listed first below) is the required mechanism for pharmaceuticals and other non-IRS commodities unless prior approval is sought and granted by the U.S. Global Malaria Coordinator (exceptions have been granted to allow UNICEF to procure LLINs when/where it makes programmatic sense).

1. Global Health Supply Chain – Procurement and Supply Chain Management (GHSC-PSM) Malaria Task Order (TO2) – The GHSC-PSM IDIQ and Malaria task order were awarded to Chemonics in April 2015. The malaria task order supports USAID’s implementation of malaria programs through the procurement, management and delivery of high quality, safe, and effective malaria commodities; the provision of on-the-ground logistics, supply chain, and related systems strengthening technical assistance and implementation capacity; provides technical leadership to strengthen the global supply, demand, financing, and introduction of existing and future malaria commodities. PMI focus countries are required to use PMI’s central mechanism for all non-IRS commodity procurement needs. The requirement (unless granted an exception) to work with PMI’s central procurement agent is due to PMI’s stringent quality assurance and quality control standards for all pharmaceuticals and related commodities procured as well as some pre-negotiated contracts to obtain the best pricing, based on volume and pooling of orders. The central procurement agent also has flexibility in accommodating last minute order changes and the ability to handle in-country logistics, clearance procedures and if necessary, distribution needs. Their familiarity with USAID regulations and requirements is an added advantage; other procurement agents’ lack of familiarity can translate into significant delays in the arrival of commodities. The mechanism’s scope also covers in-country supply chain, pharmaceutical management, and logistics for ACTs, RDTs, ITNs, SP, etc. 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. Linda Gutierrez, COR, should be contacted for additional information on this mechanism ([ligutierrez@usaid.gov](mailto:ligutierrez@usaid.gov)).
2. UNICEF Umbrella Grant—As stated above, and only with prior approval from the U.S. Global Malaria Coordinator, PMI teams may choose to use the UNICEF Umbrella Grant to procure specific malaria commodities (e.g., ITNs for a joint campaign where UNICEF is already procuring a portion of ITNs for the campaign) where UNICEF has a country presence and is already engaged in malaria commodity procurement.

Regardless of the mechanism used, no PMI funds may be used to procure products of questionable quality; this typically precludes local procurements of commodities.

## Government-to-Government Funding for Commodities

In March 2012, USAID/Washington released the *Global Health Implementation and Procurement Reform Commodities Procurement Guidance* to better explain the Agency's role under the USAID Forward Initiative as it relates to the procurement of health commodities. In response to a growing interest by some countries to move toward a greater level of self-sufficiency in maintaining national health commodity supply chains, USAID/Washington may be supportive of the procurement of health commodities by host country governments through local systems. The Implementation and Reform guidance sets forth specific criteria for malaria commodities to be considered for local procurement. These include successfully completing a Public Financial Management Risk Assessment to identify fiduciary risks, as well as an additional programmatic risk assessment, the development of an associated risk mitigation strategy, and the inclusion of specific QA/QC measures at the level PMI employs for the procurement of its own commodities. These criteria must be met and require discussion between PMI headquarters and host-country USAID missions in order to move this new process forward while meeting all USG, PMI, Mission and country regulations, requirements and needs. To date, no PMI resources have supported local procurement by partner governments.

## Global Standards through GS1 Implementation

PMI, in coordination with other USAID health supply chain divisions, is preparing the USAID global supply chain system to implement global standards 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 ensures visibility through the supply chain in the areas of product and location identification, data capture, and master, transactional, and event data exchange. On a global level, this increases PMI's ability to maintain updated product data from suppliers. In addition, other donors such as Global Fund are looking at implementing GS1 into their supply chain, enabling smoother data exchange for the future when looking towards coordinated supply planning. GHSC-PSM is also working with suppliers for their products and packaging to be GS1 compliant, which includes a GS1 barcode for automated identification and data capture to decrease time and mistakes, therefore lowering overall costs, when shipping and receiving products in warehouses both at the global and in-country levels and ultimately at facilities if country systems have adopted these standards. It also increases exchangeability of products between countries.

PMI also supports technical assistance for implementation of global standards in country to improve visibility including identification of counterfeit products and eventually moving towards a full track and trace system. As at the global level, this is a multi-year endeavor. It depends largely on the maturity of the supply chain system and commitment of country stakeholders in driving use and adoption. It also relies on a well maintained product master to fully realize the benefits that GS1 implementation can provide. Given the relatively new position of global standards as a component of systems strengthening, it is recommended that country programs consider a Learn – Assess – Plan – Pilot – Scale approach to develop a plan that looks towards building an enabling environment for future implementation. For further information and resources on global standards, please contact Clerisse Lemke ([clemke@usaid.gov](mailto:clemke@usaid.gov)).



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# SUPPLY CHAIN MANAGEMENT

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## Introduction

According to the Council of Supply Chain Management Professionals, “supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third-party service providers, and customers.” The success of health programs is dependent on their ability to reliably and consistently supply, and thereby allowing improved access to essential medicines and commodities through a well-functioning supply chain management system. Working closely with ministries of health and NMCPs, PMI supports strengthening supply chain management systems to ensure an uninterrupted supply of safe, quality-assured commodities. Supply chain management of malaria commodities poses unique challenges due to special characteristics, including relatively limited products and typically with shorter shelf lives, complex dosing requirements, and varied demand due to the seasonality and dynamic epidemiology of malaria.<sup>168</sup> These characteristics and other considerations need to be taken into account when allocating PMI resources for activities to strengthen supply chain management systems.

PMI supports the provision of technical assistance to strengthen in-country supply chain management systems and strongly recommends leveraging supply chain strengthening support by other health elements and donors. It is essential to avoid fragmentation of supply chain system strengthening support to realize sustained supply chain systems strengthening results. Malaria-only supply chain technical assistance investments must be avoided unless malaria resources are the only element/donor resources available. Even then, a systems approach to address the key bottlenecks preventing malaria and other commodities from routinely reaching end users needs to be taken. Where other resources are available (e.g., PEPFAR, PRH, MCH, etc.) and where other health elements are relying on government systems, PMI investments must be coordinated with other USG health supply chain investments. Additionally, Global Fund recently restructured, merging its strategic sourcing and supply chain departments into a single unit with a lead that reports to the Executive Director. Country teams should be aware of Global Fund’s supply chain plans for PMI countries and identify what impact they may have on PMI supply chain investment.

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<sup>168</sup> Guidelines for Managing the Malaria Supply Chain. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/guidelines-for-managing-the-malaria-supply-chain.pdf>

## Logistics Management Information Systems

A logistics management information system (LMIS) is the foundation of a supply chain management system. Improving data visibility along the entire supply chain is critical to improving overall supply chain performance, forecasting accuracy, optimizing inventory levels, and improving supply chain accountability. Strengthening LMIS and warehouse management systems is the second highest USAID supply chain investment only following commodity procurement in terms of cost. Country teams should prioritize strengthening LMIS in their supply chain funding.

An LMIS is the system of records and reports that is used to collect, organize, and present logistics data gathered across all levels of the system. An LMIS enables logisticians to collect the data needed to make informed decisions around procurement that affect product availability for health service delivery. LMIS data can be used to track trends in overall consumption, enabling more accurate forecasting and allowing adjustments to be made to country procurement plans and to in-country distribution plans. LMIS data can also be used to identify trends in dispensing practices or to detect anomalies in consumption practices. When used together with HMIS data, LMIS data can provide insight around expected correlations between services data and logistics data. In fact, PMI has country examples where correlating HMIS and LMIS data has led to detection of ACT theft at facility levels, which only underscores the importance of using these two data sources together when possible.

PMI provides technical assistance to NMCPs and other stakeholders to ensure the capture and consistent use of LMIS data. PMI country teams are encouraged to participate in discussions concerning the consistent use and improvement of an LMIS. Given that LMIS systems are integrated, multiple stakeholders are involved in these efforts and PMI should coordinate support and participate in discussions with these other stakeholders. Electronic LMIS (eLMIS) systems have been established in some PMI-supported countries. The time and budget required to implement an eLMIS is dependent on the existence and level of functionality of a paper based LMIS already established in country. Multiple LMIS software options are available to countries interested in an eLMIS but the business processes, including clearly defined roles and procedures, should drive the choice of technology. PMI country teams should participate in discussions on whether to transition to an eLMIS to ensure all key issues are taken into consideration.<sup>169</sup> For example, leadership support from the MOH or other local group, internet access, IT support, current supply chain SOPs, computer access, etc. should be taken into account when transitioning to an eLMIS system.

Based on the maturity of a country's LMIS, PMI's investment should evolve. For example, countries with weak or no systems efforts should focus on establishing a basic system of

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<sup>169</sup> eLMIS Selection Guide :Electronically Managing Supply Chain Information. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/elmis-selection-guide-electronically-managing-supply-chain-information.pdf>

recording and reporting logistics data, and then build in automation (eLMIS) as far down the supply chain as feasible. With a system in place the focus may shift to, improving reporting rates through supervision, and using data visualization (e.g., dashboards) to improve supply chain decision-making.

## Product Selection

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

## Quantification

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to ensure an uninterrupted supply for the program. This is usually done in two steps. First forecasting total need and then developing a supply plan that builds in existing inventory, current orders, and available funding from all sources. The supply plan determines the quantity and frequency of orders/shipments. Countries may use a variety of tools, including the RBM forecasting tool, which is often used for Global Fund concept notes. Three types of data can be used for forecasting: consumption data, services data, and demographic data. PMI supports use of all three types of data for quantification and forecasting. Demographic data tends to provide an upper estimate whereas consumption and services data are influenced by data quality in the LMIS and HMIS, respectively, and can misrepresent need due to stockouts and misuse, although of the two, consumption data is preferred. Quantification is not a one-time event; it requires continuous monitoring and regular updating of the supply plan to adjust for changes in consumption and when shipments arrive. **It is important that PMI country teams participate in ongoing quantification exercises. Quantification exercises should also include Global Fund representation so there is one national quantification.**

PMI provides technical assistance to build the capacity of the NMCP and other country stakeholders to lead and take ownership of the quantification. In most PMI-supported countries,

this remains an area for ongoing priority attention. In general, countries should conduct annual commodity forecasts, ideally with quarterly updates of the supply plans. These forecasting exercises are also part of the Global Fund concept note preparation. PMI country teams should participate in the process of quantifying for malaria commodities, including Global Fund forecasting activities, as NMCPs are often intimately involved along with national supply chain units and PMI input from regional advisors is appropriate. Most countries either have an established Supply Chain Technical Working Group or a Logistics Management Unit<sup>170</sup> that is charged with this responsibility, in addition to general coordination of malaria supply chain management. Once quantification and forecasts have been developed, periodic (quarterly) reviews of supply plans should be conducted to ensure timely adjustments are made based on actual deliveries, consumption patterns, and planned procurements.

PMI teams should use the country's annual quantifications as a starting point when preparing the MOP gap analysis tables.

## **Warehousing, Storage, and Distribution**

The purpose of a storage and distribution system is to ensure physical integrity and safety of products and their packaging as they move from the central storage facility to service delivery points. A sound system will preserve quality of products and will protect products from excessive heat, direct sunlight, moisture, water, pests, pilferage, and expiry. A sound system will have sufficient warehousing space that meets Good Distribution Practices standards, for all products at all levels of the system. Policies will be in place to prevent expiries (e.g., first-to-expire, first-out or procedures for what to do with short-dated stock, etc.) Procedures and policies should also be in place for waste, management, disposal, and product recall.

PMI supports the use of local in-country warehousing and distribution systems, usually through a government-owned or parastatal central medical store. As part of agreements between the USG and country governments, USG-funded commodities are exempt from all taxes. With prior approval, PMI resources can be used to pay for service fees related to warehousing and distribution of malaria commodities if there are clear agreements that describe the use of these funds. Fees for storage and distribution range from between 5 and 15 percent based on services provided (e.g., some central medical stores only deliver to the provincial or district level while others clear, store and deliver to the health facility level). Payment of these fees requires pre-approval by the U.S. Global Malaria Coordinator. Please contact Linda Gutierrez ([lgutierrez@usaid.gov](mailto:lgutierrez@usaid.gov)) for more information on obtaining prior approval for the payment of service fees for warehousing and distribution. Where transparency and accountability is in place, PMI uses government owned or managed warehouses and distribution systems (e.g., central

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<sup>170</sup> Logistics Management Units: What, Why, and How of the Central Coordination of Supply Chain Management. <https://www.pmi.gov/docs/default-source/default-document-library/tools-curricula/logistics-management-units-what-why-and-how-of-the-central-coordination-of-supply-chain-management.pdf>

medical stores). In these cases, PMI will provide technical assistance to ensure supply chain management systems maintain or improve their performance, efficiency and accountability.

Where accountability and transparency are not in place or where storage and distribution systems do not meet Good Distribution Practices standards, PMI will support the use of parallel warehousing and distribution mechanisms that are outside of government owned or government managed systems. Use of parallel systems should be coordinated with other health elements, where appropriate. Approval from the U.S. Global Malaria Coordinator is required for PMI-supported countries to shift from reliance on government systems to supporting private and/or parallel warehousing and distribution systems particularly given PMI's priority for strengthening government capacity and systems, and the often significant increased costs of supporting particularly parallel systems. While using private mechanisms, PMI provides technical assistance to strengthen the capacity of public mechanisms, with the long term goal of transferring PMI funded commodities into strengthened public systems.

A number of countries are moving away from directly operating warehousing and distribution for the public health supply chain and instead are outsourcing these services to private logistics providers. **PMI encourages use of private sector for supply chain.** Where countries have shifted to outsourced supply chain services, technical assistance focus should shift from building public sector warehousing and distribution capacity to strengthening contract management of third party logistics providers and oversight of the supply chain.

Funding for direct warehousing and distribution services, either paid to parastatals or implemented by a supply chain partner, should be included in a separate line from commodity or pharmaceutical management technical assistance costs.

## Quality Monitoring

As described above, quality, safety, and efficacy issues continue to be a major concern and top priority in the procurement of all malaria pharmaceuticals. Quality is important not only prior to shipment, but throughout the supply chain and logistics cycle, through to the end user. PMI country teams should work with NMCPs to ensure that QA standards are adhered to throughout the logistics cycle and any concerns are addressed. While significant resources have gone toward ensuring only good quality products enter malaria public supply chains, support for drug and RDT quality monitoring of products once in circulation is also critical. Historically, PMI support toward this has focused on surveillance for both antimalarial availability and quality, in both the private and public sectors.

An important component of the quality assurance continuum is post-marketing surveillance (PMS), which can provide general information not only on the relative quality of medicines circulating in the market, but also help pinpoint weaknesses with the supply chain. When considering whether this is an appropriate use of PMI funds, country teams should take into

account the scope/scale of interest, sampling methodology, private vs public market, and as importantly, intended use of data after collection and the longer term strategy for implementing a PMS activity. As a one-off activity, data collected will have little use, unless used to highlight an acute known or suspected problem (e.g., collaboration with USAID's OIG, for example). Moreover, there are a limited number of partners whose relevant scopes of work that can accommodate these activities.

It is also important to distinguish PMS from pharmacovigilance, Pharmacovigilance is a complex series of processes generally used to establish causal relationships between a previously unknown adverse drug reaction (or any drug-related problem) and a specific drug once the drug is circulating among the general population.<sup>171</sup> And while a critical part of both a mature drug regulatory system and meaningful public health program, even nascent pharmacovigilance activities require substantial financial and human capital; it should not be confused with basic post-marketing surveillance activities. To establish and maintain a functional pharmacovigilance system requires significant support over an extended period of time. Please contact Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)) for concerns around any of the aforementioned quality-related issues.

## Monitoring and Supervision

To ensure optimum performance, supply chain systems should be monitored and evaluated on a regular basis. PMI country teams should work closely with program managers and supply chain managers to review data across all levels of the system to improve system performance. The Supply Chain Technical Working Group or LMU is a good venue to facilitate monitoring and evaluation of supply chain system performance. In addition to typical monitoring and supervisory tools recommended for all supply chains (e.g., LMIS reports, supervisory checklists, etc.), PMI uses malaria-specific tools to routinely monitor the supply chain system.

- **The Procurement Planning and Monitoring Report for malaria (PPMRm)** provides data on central-level stock availability for critical malaria commodities (ACTs, SP, injectable artesunate, and RDTs). The report describes stock status of anti-malarial products on a country-by-country basis and is produced quarterly by PMI's central procurement and supply chain management mechanism. Data are used by PMI to highlight and address needs and potential supply challenges, including stockout situations through the provision of critical emergency shipments. All PMI-supported focus countries are required to provide data for the PPMRm, and PMI country teams should routinely review their countries' PPMRms to flag low stocks. The PPMRm can be accessed at [www.ppmrm.org](http://www.ppmrm.org). Please contact Clerisse Lemke ([clemke@usaid.gov](mailto:clemke@usaid.gov)) with questions or to set up a user account.

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<sup>171</sup>WHO defines pharmacovigilance as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem."

- **End-Use Verification (EUV) Survey:** PMI must ensure that USG-procured malaria commodities are reaching health facilities and are available to end users. The EUV Tool, or another tool that monitors the availability of malaria commodities at the facility level, should be used in a sample of health facilities in all PMI-supported countries two to four times a year. Stockouts of key malaria commodities should be followed up and quantification, procurement, and logistic issues resolved as soon as possible. Depending on how the sample is taken, nationally representative estimates are possible. When not representative, the estimates produced by the EUV Tool in a given quarter/semester are meant to give a general picture of malaria commodity availability at district or sub-district levels and encourage timely action to correct problems. Countries are encouraged to reach out to the PMI HQ EUV team and their supply chain technical assistance partner to discuss the best sampling approach, while also keeping in mind costs. Please consult with Christie Hershey ([chershey@usaid.gov](mailto:chershey@usaid.gov)) and Lia Florey ([lflorey@usaid.gov](mailto:lflorey@usaid.gov)) 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 EUV HQ team and Agency Leads. Countries requesting to stop the EUV must have another system of providing routine commodity availability data from health facilities to PMI HQ.
- **Task Order Malaria (TOM) Table:** PMI monitors the status of its commodity orders through the Task Order Malaria (TOM) table produced weekly by PMI's central procurement mechanism. The TOM table provides information on each active order (i.e., orders remain on the TOM table until two weeks after delivery), including order quantities, agreed delivery dates, and expected delivery dates by country. PMI country teams are encouraged to review orders on a regular basis and reach out to its supply chain backstop with any questions. Please contact Clerisse Lemke ([clemke@usaid.gov](mailto:clemke@usaid.gov)) with any questions on the TOM table.

## Supply Chain Assessments

Countries may periodically need to assess their supply chains. This is often done for evidence-based investment and planning or for performance management. Supply chain assessments should be integrated across health elements and not be malaria specific. There are various tools that can be used to conduct a supply chain assessment. One such tool is the National Supply Chain Assessment (NSCA), a comprehensive toolkit that assesses the capability and performance at all levels of a health supply chain. There are three parts to an NSCA: supply chain mapping, capability maturity model, and key performance indicators (KPIs). Please contact Christie Hershey ([chershey@usaid.gov](mailto:chershey@usaid.gov)) with questions on the NSCA or other supply chain assessments.

## Capacity Building

The performance of supply chain systems is reliant on adequately trained and motivated personnel. Without properly trained supply chain management personnel, system breakdowns

can occur resulting in poor performance of the system or product stockouts. To ensure supply chain systems staff are properly trained, PMI provides technical assistance to build the capacity of supply chain management personnel. Activities can include providing technical assistance to update in-service training content for pharmacy personnel and health workers. PMI also provides technical assistance to build capacity of health facility and community health workers in supply chain management. PMI country teams are encouraged to work with the NMCP and other stakeholders to identify and address human resources constraints that can negatively affect malaria supply chain systems.



# Commodity Procurement and Supply Chain Management

## Appendix 1: Commodities Costing Table

Costing Assumption in \$USD for Frequently Requested Commodities (2019)	
4.5% cost recovery included in total costs	
<b>Artemether/Lumefantrine</b>	<b>Per Treatment</b>
Artemether/Lumefantrine 20mg/120mg, Pill, Dispersible, 6x1 Blister Pack, 30 Treatments	\$ 0.39
Artemether/Lumefantrine 20mg/120mg, Pill, Dispersible, 6x2 Blister Pack, 30 Treatments	\$ 0.62
Artemether/Lumefantrine 20mg/120mg, tablets, 6x3 Blister Pack, 30 treatments	\$ 0.77
Artemether/Lumefantrine 20mg/120mg, tablets, 6x4 Blister Pack, 30 treatments	\$ 0.81
<b>Artesunate/Amodiaquine (ASAQ)</b>	<b>Per Treatment</b>
Artesunate/Amodiaquine, FDC, 25mg, 67.5mg, tablets, 3 per blister, 25 blisters per pack	\$ 0.26
Artesunate/Amodiaquine, FDC, 50mg, 135mg, tablets, 3 per blister, 25 blisters per pack	\$ 0.32
Artesunate/Amodiaquine, FDC, 100mg, 270mg, tablets, 3 per blister, 25 blisters per pack	\$ 0.47
Artesunate/Amodiaquine, FDC, 100mg, 270mg, tablets, 6 per blister, 25 blisters per pack	\$ 0.80
<b>Dihydroartemisinin/Piperaquine FDC (DHA-PQP)</b>	<b>Per Treatment</b>
Dihydroartemisinin/Piperaquine, FDC, 20mg/160mg, tablet, 3 tablet pack	\$ 1.34
Dihydroartemisinin/Piperaquine, FDC, 40mg/320mg, tablet, 9 tablet pack	\$ 3.04
<b>Pyronaridine/Artesunate</b>	<b>Per Treatment</b>
Pyronaridine/Artesunate 180 mg/60 mg Tablets 9 tablets x 10 blister x 30 envelopes	\$ 1.05
Pyronaridine/Artesunate 60 mg/20 mg Granules for Oral Suspension (Granules) 3 sachets x 30 strips x 30 envelopes	\$ 0.63
<b>Sulfadoxine/Pyrimethamine (SP)*</b>	<b>Per Tablet</b>
Sulfadoxine/Pyrimethamine 500mg/25mg, Pill, Bottle, 100 tablets	\$ 0.05
Sulfadoxine/Pyrimethamine 500/25 mg Tablet, 50 x 3 Blister Pack Tablets 150 tablets	\$ 0.15
Sulfadoxine/Pyrimethamine 500mg/25mg, Pill, Bottle, 1000 tablets	\$ 0.07
<b>Sulfadoxine/Pyrimethamine (SP) / Amodiaquine</b>	<b>Per Treatment</b>
Amodiaquine 76.5 mg + Sulfadoxine/Pyrimethamine 250/12.5 mg Dispersible Tablets, 50 x 1 SP + 3 AQ Co-Blister Tablets	\$ 0.36
Amodiaquine 163 mg + Sulfadoxine/Pyrimethamine 500/25 mg Dispersible 1 tablets, 50 x 1 SP + 3 AQ Co-Blister 1 tablets	\$ 0.39
<b>Severe malaria pharmaceuticals injectables</b>	<b>Per Amp/Vial</b>
Artemether 20 mg/mL (1 mL) Ampoule, 6 Ampoules	\$ 1.72
Artemether 40 mg/mL (1 mL) Ampoule, 1 Ampoule	\$ 2.32
Artemether 80 mg/mL (1 mL) Ampoule, 1 Ampoule	\$ 2.48
Artemether 80 mg/mL (1 mL) Ampoule, 30 Ampoules	\$ 0.21
Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9% + 2 x 5 mL Syringe) 60 mg Vial, 1 Set	\$ 3.83
Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 120 mg Vial, 1 Set	\$ 2.86
Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 30 mg Vial, 1 Set	\$ 2.42
Artesunate (w/ 1 Amp NaHCO3 5% + 1 Amp NaCl 0.9%) 60 mg Vial, 1 Set	\$ 2.42
<b>Miscellaneous</b>	<b>Per Tablet</b>
Primaquine 7.5 mg Tablet, 1000 Tablets	\$ 0.06
Chloroquine Phosphate 250 mg (150 mg base) Tablet, 1000 Tablets	\$ 0.13
Quinine Sulfate 200 mg Tablet, 1000 Tablets	\$ 0.06
Quinine Sulfate 300 mg Tablet, 1000 Tablets	\$ 0.06
<b>Severe Malaria pharmaceuticals suppositories**</b>	<b>Per Suppository</b>
Artesunate 100 mg Suppository, 2 Suppositories	\$ 0.50
Artesunate 100 mg Suppository, 6 Suppositories	\$ 0.50
Artesunate 200 mg Suppository, 6 Suppositories	\$ 0.76
Artesunate 50 mg Suppository, 6 Suppositories	\$ 0.48
<b>LLINs (Long Lasting Insecticide Nets)</b>	<b>Per Net</b>
Standard, Rectangular, white, 190 (L) x180 (W) x 170 (H) cm	\$ 2.72
PBO, Rectangular, white, 190 (L) x180 (W) x 170 (H) cm	\$ 3.62
Dual AI, Rectangular, white, 190 (L) x180 (W) x 170 (H) cm	\$ 6.02
<b>RDTs (Rapid Diagnostic Tests)</b>	<b>Per test</b>
Malaria Rapid Diagnostic Test (RDT) HRP2 (Pf) Cassette, 25 Single Test Kits	\$ 0.46
Malaria Rapid Diagnostic Test (RDT) HRP2 (Pf) Cassette, 25 Tests	\$ 0.38
Malaria Rapid Diagnostic Test (RDT) HRP2 (Pf/Pv) Cassette, 25 Single Test Kits	\$ 0.53
Malaria Rapid Diagnostic Test (RDT) HRP2 (Pf/Pv) Cassette, 25 Tests	\$ 0.46
<b>LAB (Microscopes)</b>	<b>Per unit</b>
Binocular Microscope, 4/10/40/100x, Halogen, Coaxial Coarse + Fine Adjustment, 230V	\$ 2,516.38
Binocular Microscope, 4/10/40/100x, LED, Coaxial Coarse + Fine Adjustment, 230V	\$ 1,019.89
Binocular Microscope, 4/10/40/100x, LED, Battery Operated, Rechargeable, Anti-Mold Coating	\$ 500.83

\* SP for IPTp, 3 tablets = 1 treatment. Price is per tablet

\*\* PMI recommends the use of 100 mg formulation. Please reach out to the case management team if you plan to procure another formulation

## Commodity Procurement and Supply Chain Management

### Appendix 2: Average Lead Time Table

Product Category		RO Validation	Procurement Activity	Approval and PO Release	Production Time	QA	Delivery Time	Total Lead Time (RO Creation to Delivery)	
ACTs	AL	2	8	1	14	8	10	43 weeks	10 months
	ASAQ	2	9	1	10	8	10	40 weeks	9 months
Severe Malaria Pharma	Artesunate Suppositories	2	8	1	13	8	10	42 weeks	10 months
	Artesunate Inj	2	6	1	14	10	10	43 weeks	10 months
	Artemether Inj	2	10	1	16	10	10	49 weeks	11 months
Other Malaria Pharma	Quinine Tab	2	10	1	12	8	10	43 weeks	10 months
	SP	2	10	1	18	8	10	49 weeks	11 months
	SPAQ	2	8	1	11	8	10	40 weeks	9 months
	Other Malaria Pharma (e.g., Chloroquine, Primaquine)	2	8	1	16	8	10	45 weeks	10 months
LLIN	-	4	5	2	17	7	12	47 weeks	11 months
Lab	-	2	5	1	10	0	10	28 weeks	6 months
RDT	-	2	3	1	12	5	10	33 weeks	8 months

## Commodity Procurement and Supply Chain Management

### Appendix 3: Assumptions for Quantification of Parenteral Severe Malaria Drugs

Regarding the procurement of intravenous, intramuscular, or rectal preparations of antimalarials indicated in the treatment of severe malaria, individual treatment dosages are weight-based, which can create challenges in quantifying total number of units needed. Country teams will have access to population data, stratified by age (and an understanding of estimated weight bands), which must be used when calculating severe malaria commodities needs. For parenteral artesunate, the general rule of thumb for number of vials needed per treatment is:

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

Average weights for healthy toddlers, children, young adults and adults can be found at both the WHO website and the CDC website ([http://www.cdc.gov/growthcharts/who\\_charts.htm#](http://www.cdc.gov/growthcharts/who_charts.htm#)). With the case of parenteral artesunate, as an example, one would need four (4) vials of parenteral 60-mg artesunate for an average man weighing 170 pounds, or about 77 kilos (where 1 kg = 2.2 pounds) as an **initial loading dose**. As the WHO treatment recommendation calls for a **total of three (3) parental doses over 24 hours**, the dosing schedule in this example would therefore be four vials initially, followed by the second dose of four vials 12 hours later, followed by the third and final dose 24 hours after the initial dose, again of four vials. That would be a total of 4 vials x 3 doses = 12 vials total to treat one average sized man using the 60-mg preparation.<sup>172</sup>

For rectal artesunate dosing, WHO treatment guidelines, third edition, recommend a 10 mg/kg pre-referral dosage. Per the October 2017 WHO information note, if using a 100 mg suppository, this would be one suppository for children 2 months up to 3 years and two suppositories for children 3 years up to 5 years. Available preparations include 50-, 100- and 200-mg capsule suppositories. 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 extent of roll out and patient population accessing pre-referral services.

For other injectables, such as quinine and artemether, both will also rely on patient weights. When country teams are putting together requisition order forms in advance of procuring parenteral severe malaria commodities, the PMI Headquarters Supply Chain Team (which

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<sup>172</sup> Injectable artesunate has two administration routes: intravenous (as a bolus) or intramuscular. Also of note: although there are three WHO-prequalified strengths of injectable artesunate, only the 60- and 120-mg dosage formulations are available for public sector procurement. The 30-mg dosage formulation is only offered for private sector procurement by the WHO-approved manufacturer, Guilin.

includes a clinical pharmacist) can be available for consultation to help prepare accurate requests (based on available data).

For questions about quantification of these drugs, please contact Jennifer Wray ([jwray@usaid.gov](mailto:jwray@usaid.gov)).

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# ELIMINATION

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## \*New/Key Messages\*

In 2017, WHO published an updated *Framework for Malaria Elimination*<sup>173</sup>, revising its recommended terminology and strategy placing all endemic countries on a continuum of transmission. This framework no longer uses the term pre-elimination previously defined as test-positivity rate less than 5% (of all febrile patients tested) throughout the year. As the PMI Strategy 2015-2020 includes an objective on pre-elimination, PMI is maintaining this term solely for tracking progress towards this objective through 2020. Going forward, PMI will align its terminology with that recommended by WHO.

Although many PMI countries have areas of very low transmission, efforts to move towards elimination will not be successful unless the necessary financing, health systems, and human capacities are in place to implement and track elimination activities.

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.

As countries approach elimination, the purpose of entomological monitoring shifts to focal investigations in areas of residual transmission and interventions tailored to particular environmental characteristics and site selection for entomological monitoring becomes more dynamic and driven by epidemiological data.

Timely, complete, and accurate recording and reporting of passively-detected, confirmed malaria cases diagnosed in both the public and private sectors is the foundation for tracking progress and identifying cases and foci for additional, intensified response measures in elimination settings.

The role of new tools and approaches, such as focal or mass drug administration and highly-sensitive diagnostic tests, remains unclear and, therefore, they are not recommended for routine implementation. PMI is conducting operational research to identify their appropriate application and feasibility, where appropriate.<sup>174</sup>

Tafenoquine, an 8-aminoquinoline like primaquine, was approved by the FDA in 2018 for the radical cure of *P. vivax* administered as a single dose, but is not yet registered in any PMI-focus countries.

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<sup>173</sup> <http://www.who.int/malaria/publications/atoz/9789241511988/en/>

<sup>174</sup> More information on mass drug administration can be found in the **Vaccines and Other Preventive Approaches** chapter of the technical guidance.

Countries that have strategies for elimination (e.g., Burma, Cambodia, Ethiopia, Madagascar, Senegal, Thailand/Regional, Zambia, Zanzibar, Zimbabwe) should ensure that elimination goals, objectives and targets, and the geographic focus of those efforts are included in their FY 2020 MOPs.

## Introduction

In the past several years, as worldwide morbidity and mortality due to malaria have continued to decline, the global malaria community has increasingly embraced the feasibility of national and regional malaria elimination, and the longer-term vision of eradication. Over the past century, more than 100 countries, including the United States, have eliminated malaria from within its borders. Most recently, several countries in WHO's Eastern Mediterranean and American Regions, and the entire European Region have interrupted local transmission and have been or are being certified by WHO as having eliminated malaria. Although elimination is being achieved in many regions, most PMI countries in sub-Saharan Africa continue to focus on control and further reduction of malaria mortality. Within the context of this scale-up, a subset of PMI-supported countries have made tremendous progress in reducing malaria mortality and morbidity and are now building the systems required to move towards elimination.

In 2015, three noteworthy global policy documents were released—the WHO's Global Technical Strategy for Malaria 2016-2030, the RBM Partnership's Action and Investment to Defeat Malaria 2016-2030, and the multi-partner *From Aspiration to Action: What Will It Take to End Malaria?*—that advocate for countries to set goals for malaria elimination and for global eradication, and outline key operational, technical, and financial strategies to achieve the longer-term vision of malaria eradication. PMI shares the global, long-term vision of “A World Without Malaria.”

The *PMI Strategy 2015-2020*, also released in 2015, sets as one of its three objectives: *To assist at least five PMI-supported countries to meet the WHO criteria for national or sub-national pre-elimination by 2020.* Pre-elimination phase, as previously described by WHO, includes areas where universal coverage of preventive and case management interventions has resulted in reduced malaria transmission to a level where monthly test-positivity rate remains less than 5% (of all febrile patients tested) are confirmed to carry malaria parasites each month throughout the year and health information systems are in place to track that progress.

In 2017, WHO released its updated *Framework for Malaria Elimination* that includes updated recommendations on terminology and classification of the stages as countries transition towards elimination. Among those changes, the term pre-elimination is no longer recommended for use. To align with this recommendation, PMI will only continue to use the term pre-elimination to monitor against the objective in its current Strategy. For other contexts, PMI headquarters and

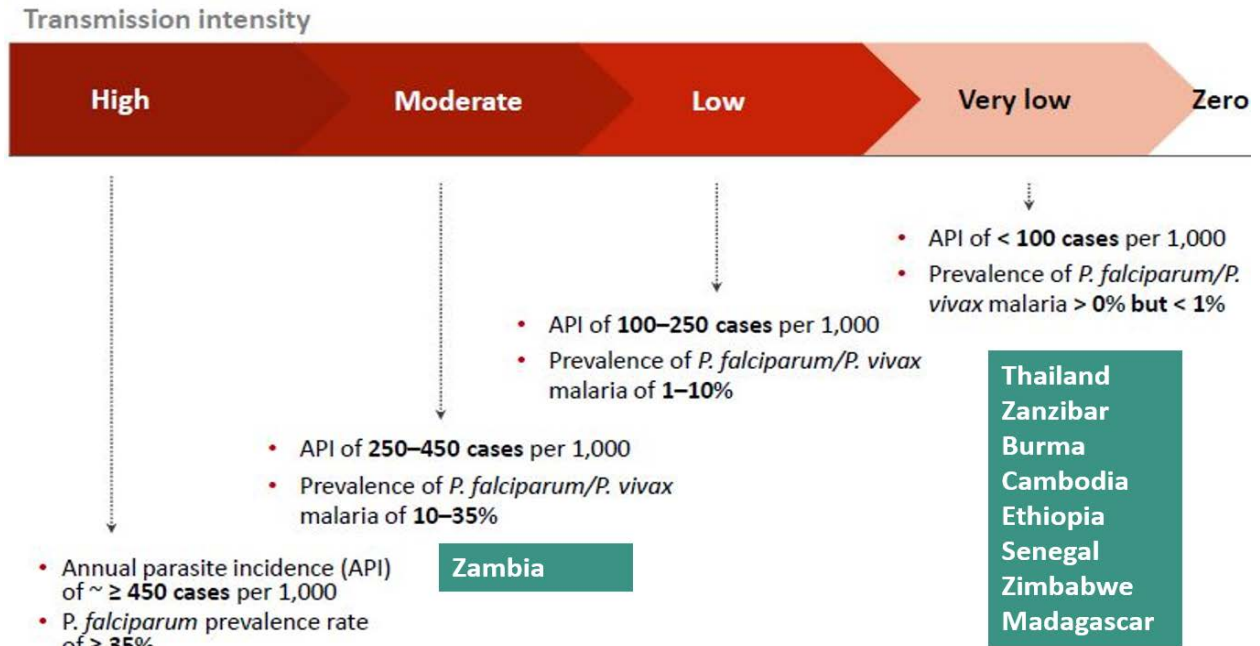
country teams are encouraged to align terminology and tracking of country progress with WHO's updated guidance.

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 case management. As malaria-affected countries fully scale up core control interventions, it is likely that some areas will witness significant reductions in malaria burden while burden remains high in others. Therefore, malaria control and elimination activities must increasingly be tailored and focalized based on malaria risk stratification to address the specific needs of areas with differing epidemiologic profiles. This can only be accomplished if countries have the capacity to collect, analyze, and interpret real-time, high-quality health management information system (HMIS)/malaria surveillance information.

The WHO *Global Technical Strategy for Malaria 2016-2030* and the *WHO Framework for Malaria Elimination* emphasizes that the progression towards malaria-free status is a continuous process. It recognizes that countries, subnational areas, and communities are situated at different points on the path towards malaria elimination, and their rate of progress will differ and depend on the level of investment, biological determinants (related to the affected populations, parasites, and vectors), environmental factors, and the strength of health systems, as well as social, demographic, political, and economic realities. The new strategy lays out a pathway to malaria elimination that notes the increasing heterogeneity of malaria transmission as intervention coverage increases and the burden of malaria decreases and the performance of national health systems as a key determinant of the rate of progress along the path.

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 1**). This reorientation emphasizes that all countries, regardless of where they lie on that continuum, should have a long-term vision of malaria elimination.

**Figure 1. Indicative Categories of Transmission Intensity and Categorization of Relevant PMI Countries/Areas**



Source: WHO *Framework for Malaria Elimination*, 2017; World Malaria Report 2018

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 **Table 1**).

**Table 1. Tracking Progress and Capacity in Reaching Elimination in PMI-supported Countries/Areas**

Country/Area	POLICY		IMPLEMENTATION		ROUTINE DATA*			
	Pre-/ Elimination Strategy	Risk Stratification	Cases investigated	Foci investigated	API	Test Positivity Rate	Case Confirmation Rate	HF Reporting Rate
Thailand	Green	Green	Green	Green	<1	<5	100	100
Zanzibar	Green	Green	Yellow	Yellow	1-10	<5	100	92
Myanmar/Burma	Green	Green	Yellow	Yellow	1-10	<5	100	100
Cambodia	Green	Yellow	Yellow	Red	10-100	5-50	100	100
Ethiopia	Green	Green	Yellow	Red	10-100	5-50	87	97
Senegal	Green	Green	Yellow	Yellow	10-100	5-50	99	100
Madagascar	Yellow	Yellow	Yellow	Red	10-100	5-50	82	95
Zimbabwe	Green	Green	Yellow	Yellow	10-100	5-50	100	100
Zambia	Green	Yellow	Yellow	Yellow	>100	>50	90	92

\*Limited to the public sector

Source: WHO *World Malaria Report* 2018 and FY 2019 MOPs

Color coding: Green- target achieved, Yellow- progress toward target, but target not achieved, Red- significant progress needed



Once programs have reduced transmission to very low levels, they should assess the technical, operational, and financial feasibility of elimination and the programmatic capacity, including the ability of surveillance systems to track and manage every case of malaria infection necessary to eliminate malaria. The following factors and associated indicators along with their necessary technical capacities will be important to consider for countries to monitor progress towards elimination:

**Technical Feasibility:**

- Data that suggest successful implementation of malaria control interventions
  - *Relevant survey indicators: ITN/IRS coverage, treatment-seeking within 24 hours of fever onset, and malaria prevalence*
- 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
  - *Relevant routine indicators: number of cases and deaths, Annual Parasite Incidence (API), test positivity rate, case confirmation rate*
- Ability to ensure ongoing high-level coverage of vector control interventions
- A surveillance, monitoring, and evaluation system able to identify, investigate, and control malaria hotspots, rapidly respond to malaria cases, and reliably measure elimination targets
  - *Relevant routine indicators: completeness and timeliness of HMIS and malaria information system, proportion of cases and foci investigated*
- Enabling environment with strong community engagement, political commitment and collaboration amongst relevant ministries and key private sector stakeholders

**Financial Feasibility:**

- Strong political commitment evidenced by dedicated, sustained funding (both domestic and external) to achieve and maintain malaria elimination

PMI and other partners have developed new tools including Ethiopia's Malaria Elimination Baseline Assessment Tool that are intended to systematically assess the system and human capacity readiness at national and sub-national levels to move towards elimination. An evaluation of the technical and operational situation using such tools is an essential first step in planning and implementing elimination activities. The findings of assessments using such tools will provide programs with necessary information on what areas require further strengthening, which will enable better prioritization of PMI and country resources. Anyone interested in learning more about these tools and its potential adaptation and use in other countries can contact the PMI Elimination Working Group.

## Shrinking the Malaria Map

The worldwide malaria map continues to shrink with global economic development and increasing political and financial support for control and elimination. The specific measures to be applied in order to achieve malaria elimination and national goals and targets will always be governed by local conditions. Within its allocated funding envelope, PMI will support evidence-based national strategies and approaches. This will largely continue to focus on scaling up and sustaining control interventions. However, in applicable countries, additional support to further prioritize strengthening surveillance systems and operational research to determine cost-effective and feasible elimination approaches are being implemented. **In countries where malaria burden varies significantly in different areas 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.** These control efforts focused on high transmission areas will be crucial in limiting the exportation of source cases to elimination areas within the country.

## High-Risk Populations Within Elimination Settings

As malaria burden decreases in a country, spatial heterogeneity, as well as new demographic risk factors, will become increasingly relevant. Often, it is not uncommon that certain groups may continue to carry a higher burden of malaria despite reductions in the general population. Examples of such emerging high risk groups include indigenous people in Central and South America, ethnic minority groups and forest workers in the Greater Mekong Subregion, and migrant agricultural workers in Ethiopia. These groups share some common characteristics, including geographic isolation from or reduced access to mass media and public health structures and preventive tools, lower wealth status and literacy, poorer housing, and increased movement for economic pursuits. In some instances, particularly in farm and forest workers, their work requires them to move from lower to high risk areas and to carry out activities, including working outdoors during peak mosquito biting times, which increases their risk of infection.

Reaching these populations can be particularly challenging, as they may only stay in one location for a few weeks or months or may be conducting unsanctioned work, which leads them to avoid contact with any government authorities or facilities. These groups also tend to have lower literacy or may speak a different language, and are likely unaware of the availability of health services in their temporary locations, unless the farm or plantation provides those services. In some settings, traditional control measures, like standard LLINs and IRS, may not be appropriate for their living and work situations.

Migrant and mobile populations may also be inadvertently excluded from net distribution or household surveys, as they do not appear on the local census which is used as a basis for population estimates in both situations.

Innovative approaches must be developed and tested to both identify and reach these high-risk populations. Examples of approaches that have been piloted in PMI focus countries include:

- Providing LLINs to farm/plantation owners to distribute to their workers
- Setting up farm/plantation/forest clinics/workers or training mobile 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 materials for use in cross-border settings
- Establishing border health posts
- Employing novel surveillance approaches to capture testing and treatment data so that these high-risk groups are accounted for in monitoring and evaluation efforts

## **Entomological Monitoring and Vector Control**

In high-transmission areas, longitudinal entomological monitoring via fixed sites is necessary and cost-effective given the likelihood of finding mosquito vectors at a particular site is high. Thus, where one samples is less important than sampling consistently and rigorously. In contrast, marked heterogeneity in malaria transmission within regions and even neighboring foci becomes apparent as transmission decreases. Furthermore, vector numbers may decline markedly, making mosquito collections more time-consuming and costly. Heterogeneity and sparse vectors 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.

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 foci while those where local transmission has not been observed for at least three years are considered cleared. The entomological monitoring and vector control strategies should be tailored to the status of each individual focus. Vector control should be maintained in both active and residual non-active foci. For cleared foci, the receptivity and vulnerability of the area should be assessed along with the capacity for the health system to respond to malaria outbreaks before vector control is ceased. The strategy for entomological monitoring should also be adjusted according to the classification of foci.

### *Site selection for entomological monitoring*

In elimination settings, decisions as to where entomological monitoring should be carried out should be based on malaria burden data, whether passively collected case data or prevalence survey data. 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. In residual non-active foci or cleared foci where transmission has been interrupted, continued entomological monitoring is likely to be of little value. Nonetheless, limited longitudinal fixed site monitoring may be useful to maintain vector monitoring capacity and to train field staff. The PMI Headquarters Vector Monitoring and Control Team will help advise for specific elimination settings. For further information on the needed components of entomological monitoring, refer to the **Entomological Monitoring** chapter.

Entomological investigations may be implemented in active foci that have persistent transmission despite high coverage of vector control interventions. These active foci should be targeted for entomological investigation based upon aggregate API reported through the routine health system. Time-limited entomological investigations may also be warranted in residual non-active or cleared foci in response to outbreaks. These entomological surveys should be done in conjunction with epidemiological investigations to assess intervention coverage and human behaviors that may result in increased risk of malaria. If no clear risk factors are identified during the initial assessment, a more detailed entomological assessment may be necessary, as the increase in cases may have been the result of a failure or reduced effectiveness of vector control interventions.

### *Role of entomological monitoring in support of vector control*

The common vector control interventions broadly scaled up in control areas – LLINs and IRS – should be targeted to areas where transmission is ongoing in elimination settings. It should be noted that even if a mosquito population shows tendencies to bite or rest outdoors, that indoor interventions can still have a significant impact on the population as a whole since indoor and outdoor biting populations are not distinct (i.e., within a mosquito's lifespan it is likely to try to feed/rest for at least a short time indoors where it could come in contact with an insecticide treated net or surface). Although no clear criteria exist for stopping LLIN distribution, WHO recommends that vector control intervention coverage should be maintained at least until transmission has been fully interrupted and, if feasible, beyond that point, to minimize the risk of reintroduction. In the case of Ethiopia, for example, districts with an annual parasite incidence of <1 case/ 1,000 population will not receive LLINs in their upcoming mass distribution campaigns. If vector control measures are withdrawn, countries must ensure that malaria case surveillance systems are in place to monitor the situation closely.

As malaria transmission declines, recalcitrant foci of transmission or hotspots may emerge. Investigation of such foci should:

- 1) Determine coverage of standard interventions – whether LLINs or IRS plus case management – followed by prompt corrective action should coverage be low
- 2) If coverage is high and transmission is ongoing, then epidemiological and entomological investigations should be conducted to determine the source of residual transmission which is defined as persistence of transmission after good coverage has been achieved with high-quality vector control interventions to which local vectors are fully susceptible.<sup>175</sup>
- 3) Entomological investigations should include:
  - a. Vector discrimination
  - b. Insecticide resistance monitoring

If residual transmission appears to be associated with certain occupations (e.g., forestry, mining, or agriculture), investigations should focus on identifying high risk behaviors 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. In some cases, it may also be necessary to assess the resistance profile of the predominant vector, should this be feasible.

If LLINs and IRS have been fully implemented in targeted foci and transmission continues, interventions that may not be appropriate in a control context, where broad scale coverage is needed, may be needed in elimination settings to tackle residual transmission; these may include interventions targeting larvae as the rubric of ‘fixed, few, and findable’ may be less relevant in a severely circumscribed focus when the object is malaria elimination.

Because residual transmission may be occurring away from houses or outdoors, operations research to determine the acceptability, feasibility, and effectiveness of additional non-standard interventions to address residual transmission (e.g., insecticide treated clothing, repellents, or other vector control approaches such as larval source management) may be needed. **PMI’s support for implementing such interventions would depend on evidence that such interventions are effective in the specific geographic/ecological/epidemiologic context and may require that such strategies first be evaluated through OR.**

## Malaria in Pregnancy

The impact of malaria infection on the health of the pregnant woman and her developing fetus depends to a large extent on the level of malaria transmission in the region in which she lives. In low-transmission areas or epidemic areas, women may be less exposed, particularly when

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<sup>175</sup> WHO Malaria Terminology. WHO Global Malaria Programme.

transmission is related to specific occupational risks. Consequently, pregnant women will have little or no acquired immunity, and are more likely to present with clinical malaria (although asymptomatic infection can still occur). They are also at an increased risk of anemia and severe malaria. Even in very low transmission settings, MIP is associated with spontaneous abortion, stillbirth, prematurity, and low birth weight. For these reasons, all PMI-supported countries, regardless of transmission levels, should continue to address prevention and control of malaria in pregnant women and ensure effective case management.

## *Prevention*

### ITN

Countries proceeding towards elimination should continue to provide ITNs to pregnant women both through campaign distributions and through routine antenatal care depending on the country's distribution strategy. In countries, which do not currently implement IPTp, ITNs are the only preventive measure that can be applied throughout the pregnancy.

### IPTp

In many PMI-supported countries, transmission has been substantially reduced due to effective prevention and control measures. Some PMI-supported countries (e.g., Kenya, Madagascar, and Zimbabwe) have opted to implement sub-national or focal IPTp policies targeting only moderate/high burden areas. As malaria burden decreases in countries, questions have arisen around the continued effectiveness of IPTp in low transmission settings. **The WHO currently recommends that countries in Africa that have reduced malaria transmission should maintain IPTp as a preventive strategy for pregnant women and PMI supports this recommendation.** Currently, there is insufficient data to determine a transmission threshold below which IPTp is no longer cost effective or efficacious. IPTp with SP remains safe, effective, and relatively inexpensive to implement. In addition, recent data has shown the deleterious effects of even low-level infections on pregnant women and their babies. Therefore, PMI will continue to support the implementation of IPTp-SP in all countries where it is currently part of the national strategy regardless of decreasing levels of malaria transmission to pre-elimination levels.

Outside of Africa, there is not sufficient evidence to support IPTp-SP as a prevention strategy and countries are encouraged to focus on ITN provision to pregnant women and prompt health care seeking for fever.

## *Case management of pregnant women*

As with all suspected cases of malaria, parasitological confirmation by RDT or microscopy is recommended. The treatment protocols for uncomplicated and severe malaria in pregnancy for low transmission or pre-elimination settings are the same as recommended for high transmission

or endemic areas. Appropriate management of vivax malaria during pregnancy needs to include, when feasible, strategies to prevent relapses without the use of primaquine.

### ***Other interventions: ISTp and MDA***

Recent studies have shown that ISTp is not as effective as IPTp-SP in reducing the malaria burden in pregnancy for African settings where *P. falciparum* is prevalent. ISTp was associated with more maternal clinical malaria episodes, and was more costly when compared to IPTp-SP. An ISTp study in Rwanda also showed that it was not superior to a clinical case management approach (i.e. only testing symptomatic women). In certain settings (e.g., Asia), where *P. vivax* is common and IPTp-SP has not been deployed, the alternatives are less clear and further evidence is needed. Although methods of detection of parasitemia (peripheral or placental malaria smear, RDT, or histopathology) underestimate the burden of malaria in pregnancy even in low transmission settings, available evidence indicates that if screening is done, it will be most effective early in pregnancy.

Care must be taken when deploying strategies such as mass drug administration<sup>176</sup> to avoid inappropriate treatment of pregnant women, particularly during the first trimester of pregnancy. This may pose a challenge since it requires the identification of women in early pregnancy who may not yet appear to be pregnant or may not disclose this information. Screening, including offering pregnancy tests and/or conducting an interview to ask about pregnancy status directly, may not be an optimal approach as many women may not wish to reveal their pregnancy status. Given that approximately 20% of the population is comprised of women of reproductive age who may be pregnant, the number of women who need to be screened for pregnancy is substantial across countries. In addition to privacy issues, costs of screening may be another barrier. Recent MDA pilots have excluded infants and pregnant women from receiving the intervention. It is also important to note that primaquine is contraindicated in pregnancy and lactating women. PMI-supported countries considering some of the newer approaches to control of malaria in pregnancy should consult with the relevant PMI Headquarters teams (Elimination, Case Management, and MIP) in the planning phases of such activities.

## **Case Management**

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.

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<sup>176</sup> Please see Other Preventive Approaches for more detailed description of Mass Drug Administration.

## *Diagnosis*

As in any other setting, the diagnosis of a clinical case of malaria both at facility and community levels should be based on the result of a diagnostic test, either microscopy or RDT. When performed and interpreted correctly, both microscopy and conventional RDTs can detect parasites for *P. falciparum* and *P. vivax* in concentrations at or above 200 parasites per microliter, which is sufficiently sensitive for identifying parasitemia in patients with clinical symptoms. Highly sensitive RDTs (hsRDTs) are now available and may be useful for certain indications in elimination settings. The hsRDT developed by Abbott detects only the HRP-2 antigen and has a limit of detection of parasite density that is about 10–20 times lower than conventional RDTs. WHO does not recommend the use of hsRDTs for clinical diagnosis and indicates that further research is needed to determine the role of more highly-sensitive tests for case finding activities. Such hsRDTs may have a role, for example, in the context of reactive case detection (see ‘*Surveillance Approaches*’ section). PMI is supporting operational research on hsRDTs for reactive case detection in Burma and Cambodia, as well as in the setting of the IPTp study in Malawi. Results from these and other studies will assist in determining whether and in what contexts these new tools may be useful. Neither WHO nor PMI recommend the use of highly-sensitive RDTs for surveillance nor diagnosis of clinical malaria cases in any setting, and will not support procurement of these tests as a replacement for conventional RDTs.

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, clinical diagnosis should be strongly discouraged, except in those cases where a delay in initiating treatment could increase the risk of severe disease or death. Even in those situations where treatment must be provided without a diagnostic test, effort should be made prior to commencing treatment to collect samples for testing at a later time. Testing could also be carried out as soon as is feasible after initiation of treatment to confirm the diagnosis although any delays in obtaining samples (e.g., more than 24 hours) would reduce reliability of a negative microscopic blood film examination. In contrast, RDTs will generally remain positive for days to weeks after clearance of parasites from the blood, particularly RDTs based on detection of the HRP-2 antigen.

As in higher transmission settings, microscopy is the preferred diagnostic test for patients with severe febrile illness, so that parasite density can be monitored, and also in cases of suspected treatment failure. In field settings, RDTs and microscopy are generally of equivalent accuracy in the hands of competent health workers.

One of the challenges in elimination settings is that the skills of laboratory technicians in malaria microscopy and RDTs can deteriorate as positive tests become increasingly rare and the parasite densities detected in samples from patients with clinical malaria are much lower than in higher transmission settings. Extra efforts must be made to maintain the skill of malaria microscopists, through periodic refresher training, frequent supervision, and establishment of a proficiency



testing program. A proficiency testing program uses panels of well-prepared, well-characterized blood slides that are periodically sent to microscopists as unknowns. The microscopists are asked to read these slides and report results to the program administrator. The reported results are compared with the known results and errors in reading addressed through follow-up supervision or retraining, as appropriate. A validated national slide bank can be used to prepare such proficiency testing panels, as well as standardized training sets. PMI should prioritize support to ensure these skills are retained in these settings.

All PMI-supported countries, and particularly those moving towards elimination, should have such a slide bank. PMI is supporting development of slide banks in a number of countries. Standardized protocols for development of these slide banks are included in the updated 2016 WHO Malaria Microscopy Quality Assurance Manual.<sup>177</sup>

The highest priority must be placed on ensuring an uninterrupted supply of essential diagnostic and treatment commodities in elimination settings, as any delay in diagnosis or treatment of a malaria case increases the risk of progression to severe illness and also onward transmission of that infection. In addition to routine supply chain strengthening, there may be a need for an urgent resupply strategy using strategically located buffer stocks and clear notification systems. District-level buffer stocks and redistribution between sites in Cambodia have successfully prevented most stockouts in PMI targeted districts. PMI should consider prioritizing support to help ensure these uninterrupted supplies, and understand that occasional expiration of small amounts of unused commodities is often unavoidable, particularly if the country is to be prepared for unexpected focal increases in malaria cases.

The need for rapid diagnosis, treatment, and response to malaria cases also necessitates quick and easy access to care for affected populations. In elimination settings, village or community health workers often become the foundation for both malaria case management and the subsequent investigations. Additional approaches, including mobile or migrant health workers, border clinics as in the E8 countries, health services provided in high risk settings (such as plantations in Cambodia or mining 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. Use of directly observed therapy (DOT), often in a modified form where each morning dose is observed by a CHW, and repeat testing with microscopy to document clearance of parasitemia after completion of treatment, are being used in some settings (particularly in the Greater Mekong Subregion,

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<sup>177</sup> [http://apps.who.int/iris/bitstream/10665/204266/1/9789241549394\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/204266/1/9789241549394_eng.pdf)

where treatment failures to ACTs have been identified and as an alternative to therapeutic efficacy monitoring in low transmission settings).

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

In 2015, WHO updated its guidelines to recommend the administration of a single gametocytocidal dose of primaquine to be given in addition to an ACT for falciparum malaria **in low transmission areas.**<sup>178</sup>

#### **WHO Recommendation (2015)**

In low transmission areas, give a single dose of 0.25 mg/kg primaquine with ACT to patients with *P. falciparum* malaria (except pregnant women, infants aged <6 months, and breastfeeding women of infants aged <6 months) to reduce transmission. Testing for G6PD deficiency is not required.

The WHO recommendation was updated from the previous 2012 recommendation, which excluded infants <1 year of age. Further recommendations include administration of single dose 0.25mg/kg primaquine on the first day of ACT treatment and with food to improve tolerability, and advice to individuals to monitor for signs of acute hemolytic anemia including dark urine and to seek medical attention should signs arise.

Previous mass administrations of a longer course of primaquine (14 days) without testing for G6PD deficiencies have been administered successfully. Based on these historical data, WHO guidance states that “Clinically significant haemolysis is not expected to occur in either G6PD-normal or -deficient individuals given a single 15-mg adult dose (0.25 mg base/kg) of primaquine” and “there is no need for systematic testing for G6PD deficiency before administering a single dose of 0.25 mg primaquine base per kg body weight”.<sup>1</sup> Specific information on symptoms and management of side effects can be found in the WHO updated policy brief.<sup>91</sup>

Even though WHO has issued guidance that G6PD testing is not required for the administration of the single 0.25 mg base/kg dose of primaquine, countries have been reluctant to adopt this policy. PMI supported a study to assess the safety of single low dose primaquine in G6PD-deficient patients in Cambodia; and other partners have conducted similar studies in some African settings, including Mali, Kenya, Swaziland, Zanzibar, Zimbabwe, and Senegal. Findings from the Cambodia study suggest that single low-dose primaquine was well-tolerated and did not result in significant decline in hemoglobin concentrations by day 7 in 9 G6PD deficient patients,

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<sup>178</sup> Policy brief on single-dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria, January 2015: [http://www.who.int/malaria/publications/atoz/who\\_htm\\_gmp\\_2015.1.pdf](http://www.who.int/malaria/publications/atoz/who_htm_gmp_2015.1.pdf)

although the number of G6PD-deficient patients was small.<sup>179</sup> Results of administering single dose primaquine during MDA in the Mekong<sup>180</sup>, and dosing of G6PD-deficient adult males without malaria in Mali<sup>181</sup> with doses up to 0.5mg/kg and G6PD-deficient children ages 5-17 years with 0.4mg/kg, have not noted any clinically significant hemolysis.

Studies show that primaquine kills gametocytes and is the only widely available drug to kill mature falciparum gametocytes, which reduces the infectivity of *P. falciparum* malaria. Population-level reductions in transmission are only possible when a high proportion of patients are treated AND there is not a large asymptomatic human reservoir. Furthermore, modeling has shown that the addition of primaquine to first-line treatment of symptomatic falciparum patients in higher transmission settings would have no impact on transmission. Therefore, PMI recommends the addition of single, low-dose primaquine only in areas of low transmission and/or in a setting with confirmed artemisinin resistance.<sup>182</sup>

### Treatment of asymptomatic infection

Asymptomatic infections are rarely identified in a clinical setting, but rather through active case-finding activities that are carried out in elimination areas. This would include case finding around an index case (reactive case detection) or community surveys (proactive case detection).

In elimination settings, any detected infection, whether symptomatic or asymptomatic, is considered a malaria case and treated as such. Treatment for asymptomatic infections would be the same as that for uncomplicated clinical cases, including the addition of low-dose primaquine for *P. falciparum*, as guided by the national malaria treatment policy.

### Treatment of non-falciparum infections

Countries outside of tropical Africa on the path to eliminating malaria will often have proportionately higher levels of non-falciparum infections, particularly *P. vivax*. Appropriate treatment begins with accurate diagnosis. Treatment of liver-stage infections caused by *P. vivax* is necessary for preventing relapses. Before primaquine is administered for radical cure, the G6PD status of the patient should be assessed. 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

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<sup>179</sup> Dysoley, L. et. al., (2019). The tolerability of single low dose primaquine in glucose-6-phosphate deficient and normal falciparum-infected Cambodians. BMC Infect Dis.

<sup>180</sup> von Seidlein, L. et. al., (2019) The impact of targeted malaria elimination with mass drug administrations on falciparum malaria in Southeast Asia: A cluster randomised trial. PLoS Med.

<sup>181</sup> Chen, I. et. al., (2018) Safety of Single-Dose Primaquine in G6PD-Deficient and G6PD-Normal Males in Mali Without Malaria: An Open-Label, Phase 1, Dose-Adjustment Trial. J Infect Dis.

<sup>182</sup> Although the recommendations did not define low transmission, the recent WHO Elimination Framework defines very low transmission as areas having an annual parasite incidence of  $\leq 100$  and a prevalence of *P. falciparum/P. vivax* of  $\leq 1\%$ . It is also reasonable to use a health facility test positivity rate of  $< 5\%$  as a threshold.

primaquine. Treatment guidelines for *P. vivax* can be found in detail in Annex 2 of WHO's 2017 "A Framework for Malaria Elimination" and its 2015 "Guidelines for the Treatment of Malaria."

Tafenoquine recently received WHO PQ for radical cure of *P. vivax* infections and is now undergoing implementation pilots in Thailand, Ethiopia, and Brazil. It is a single-dose treatment, which will certainly improve adherence. It cannot, though, be given to patients with G6PD deficiency. Therefore, quantitative assessment of G6PD levels is required before administration. The drug is currently commercially available only in the U.S. and Australia.

## Surveillance, Monitoring, and Evaluation

### *Household surveys*

PMI relies on household surveys to monitor coverage of interventions on a national or sub-national scale (for countries with large malaria-free areas), including ITN and IPTp coverage. As discussed in various chapters of this guidance, high-level coverage of these interventions will need to be sustained for elimination efforts to be successful. Therefore, PMI will continue to support periodic household surveys, every 3-5 years, as appropriate, to ensure that coverage of these critical interventions does not wane. In countries with high heterogeneity of transmission, sampling frame will need to be adjusted to ensure that surveys sample areas with malaria transmission risk. 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. These methods, though, have been difficult to conduct and appear to be less applicable in the malaria setting where social networks are less well-defined and established.

Although population surveys may still be needed in an elimination setting to monitor coverage of interventions, they become less useful for measuring morbidity. PMI has historically used national household surveys (e.g., MIS) to collect data on anemia and parasitemia, and DHS to track all-cause child mortality as impact indicators. For those countries moving towards elimination, national household surveys of a given sample size will become less sensitive to changes in parasitemia and malaria-related anemia as the prevalence of those conditions declines.

PMI recommends that in countries where parasite prevalence in children under five years of age is at or below 3% in two successive national surveys, collection of parasite burden by microscopy or RDTs and hemoglobin through national surveys should be discontinued. Exceptions can be made in countries where parasitemia has substantially declined in some regions of the country, but remains significantly greater than 3% in other regions. **Countries transitioning to elimination should increasingly use longitudinal health facility- and**

**community-based surveillance data, if of sufficient quality, to monitor seasonal and annual trends in malaria burden, as described in the surveillance section below.**

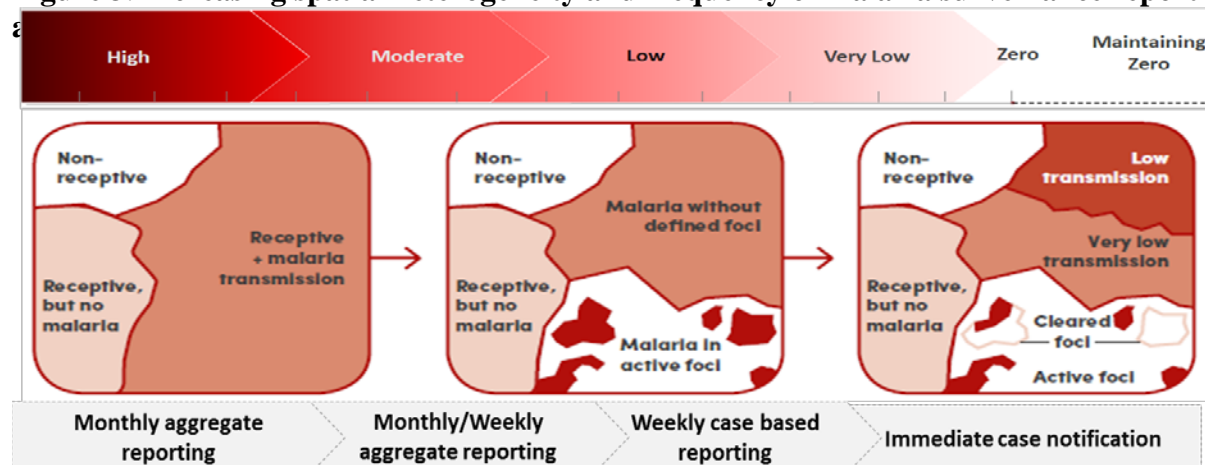
All-cause child mortality measurements obtained from national-level surveys (e.g., DHS) are used in high-burden countries as an indicator of impact of malaria control interventions. In high-burden settings, malaria contributes a large percentage of the mortality burden in children under five years of age, so a reduction in ACCM is seen as an appropriate measure of malaria control efforts. However, as countries move towards elimination, the proportion of child mortality attributable to malaria declines and ACCM is no longer an accurate indicator of progress toward malaria elimination. Countries will still need to collect ACCM as a basic demographic indicator and to measure progress in maternal and child health beyond malaria. However, PMI should bear less of the financial and logistic burden of organizing the DHS surveys in elimination settings.

As a country or region approaches elimination, stratification of malaria risk will be more important to target interventions. In most high-transmission settings, most national malaria risk maps are derived from a combination of parasite prevalence data from household surveys, and data from various other sources on rainfall, temperature, and vector ecology. Countries approaching elimination with improved surveillance systems rely on their malaria incidence data to generate and update malaria risk maps. Countries able to investigate their cases can further refine their risk maps to distinguish local from imported cases. Ecologic factors as well as robust surveillance data should be used by NMCPs to make strategic decisions regarding the deployment of various interventions, and to monitor progress towards elimination.

### *Disease surveillance*

As transmission decreases, data needs, data collection methods, and the frequency with which data are collected and reported will change. Countries' epidemiological profiles and health system capacity should be taken into consideration when developing and implementing national SM&E strategies, including those targeting elimination. Strengthening surveillance systems is a long-term process and is addressed in detail in the **SM&E** chapter. Countries in elimination are expected to have a well-functioning routine surveillance system that collects timely data which is a prerequisite for any country aiming to achieve this phase. For countries in the elimination phase, the focus of disease surveillance activities should be on strengthening malaria case detection and timely reporting along with building capacity for individual case reporting and investigation, and foci investigation and response. The increasing spatial heterogeneities as transmission decreases necessitates a shift from reporting aggregate data by month over large geographic areas (e.g., district) to reporting near real-time, individual case data over small areas (foci) (Figure 3).

**Figure 3. Increasing spatial heterogeneity and frequency of malaria surveillance reporting**



*Surveillance system requirements for elimination*

1. **Implementation of a national system to collect facility- and community-based data on confirmed malaria cases in order to reliably measure malaria incidence in all regions of the country:** Countries (or regions) approaching elimination will require a surveillance system capable of recording and reporting malaria incidence in increasingly smaller areas and timeframes. Such a surveillance system can quickly identify focal areas of continued or new malaria transmission and to facilitate rapid response to prevent outbreaks and/or epidemics. A comprehensive surveillance system will need to incorporate data from all sectors, including public, private, non-governmental organizations, military, etc.
2. **Ability to identify, investigate, and control foci of malaria transmission:** In the elimination setting, surveillance systems must be capable of timely (no less frequently than weekly) reporting of malaria cases by location of transmission. These should be analyzed for possible hotspots, or foci of transmission, to allow for targeted malaria control efforts. The investigation of the index case and subsequent response measures (reactive case detection) could include testing and treatment of family members 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 capacity:** Building disease surveillance capacity should be supported in all PMI focus countries. In elimination settings, the capacity of local health authorities to rapidly identify, investigate, and respond to outbreaks is critical. In such settings, PMI will support the training and supervision of health workers and surveillance and environmental/entomological officers to detect and report cases, investigate foci, and respond with appropriate control measures.

## *Disease surveillance tools*

### National disease surveillance systems

In many PMI countries, multiple surveillance systems exist which collect malaria data at varying frequencies. In collaboration with the NMCP and MOH authorities, PMI teams should prioritize specific areas for programmatic support. In elimination countries or regions, the focus of PMI support to surveillance systems should be on developing the critical surveillance capacity necessary to achieve timely, aggregate, comprehensive data. The following points should help in making these decisions.

Country teams should consider support to these systems based on the following conditions/contexts:

- **Integrated, health facility-based routine information systems (HMIS, IDSR—for a more general description of these systems see SM&E chapter):** Health Management Information Systems (HMIS) typically report aggregate health-facility level data on a monthly basis. These data do not have the resolution or timeliness needed for targeted elimination efforts (e.g., case listing or detection of transmission foci). In some instances, case-based surveillance tools can be integrated into HMIS via an electronic platform such as DHIS-2. In general, countries nearing elimination should have well-functioning routine aggregate data systems and will focus investments on developing timely, case-based data systems for elimination certification.

Integrated epidemiologic surveillance systems, such as IDSR, provide timely alerts (weekly or even daily if necessary) though may lack the higher-resolution data needed for individual case investigation and response. IDSR systems could be used in outbreak detection and monitoring interventions in a timelier manner.

- **Stand-alone or dual-reporting malaria surveillance systems:** Some countries have stand-alone malaria surveillance systems with more frequent reporting (e.g., weekly) than routine HMIS systems. While PMI does not generally support national parallel surveillance systems for malaria, in some instances these systems may be necessary for targeted elimination areas. Any considerations of support for parallel systems should be discussed with the PMI Headquarters SM&E and Elimination Teams and PMI leadership.

It is important to understand that HMIS and IDSR are often managed by different departments within the MOH and may have different goals and reporting frequency. Consequently, it is possible that a national malaria control program may have limited, timely access to malaria data collected through HMIS or IDSR. In countries moving towards but that have not yet reached the elimination phase, weekly IDSR reporting is likely an adequate platform and the MOH must coordinate appropriate data access for the NMCPs. However, some countries approaching the elimination phase may require a malaria-specific, supplementary surveillance system that builds

on the HMIS/IDSR platform and reports directly to national or sub-national malaria control authorities with greater frequency. These countries in the elimination phase will likely require additional systems that can accommodate individual case data collection, reporting to the national and regional levels within days of diagnosis, and detailed investigations on every case. Systems and modules to support individual case reporting and tracking are being rapidly developed, including RTI's Coconut Surveillance platform used in Zanzibar and the DHIS-2 TRACKER being piloted in Zimbabwe and Burma.

### Hardware/software

There are no specific requirements regarding hardware and software for an effective pre-elimination surveillance system. However, the ability to rapidly share data is essential when approaching pre-elimination and the use of computers and mobile phones/tablets will facilitate rapid reporting. The selection of appropriate technology needs to be in line with the data collection needs identified, the overall surveillance strategy, and the national telecommunication infrastructure and policies. Examples of surveillance tools and equipment that assist in rapid case notification, investigation and response include:

- **SMS-based reporting:** minimal case information can be entered and sent via SMS from CHW or local providers to surveillance staff to alert them to newly confirmed cases. This approach does not require a smart phone or data network to function as information is transmitted via cell phone network. This may be appropriate in locations where only the cell phone network is available.
- **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 requires functional data network.

A landscaping of currently available mobile technologies and a roadmap for mobile solutions for malaria elimination surveillance systems was commissioned by the Bill and Melinda Gates Foundation and is available at <http://vitalwave.com/case-study/mobile-solutions-for-malaria-elimination-surveillance-systems/>.

### Surveillance approaches

The following are approaches to surveillance that can be supported through PMI funding where appropriate:

- **Passive surveillance:** Passive surveillance systems rely on data on individuals presenting for care within the health system. These data are aggregated and reported on a periodic



basis (usually monthly). In elimination settings, the system ideally should include all cases in a geographic area including public, private sector, and community level data. Passive surveillance does not generally capture cases and deaths that occur outside of a health care setting, and thus might not provide a complete picture of malaria burden. In general, passive surveillance should be fully functioning and providing actionable data for a NMCP before pursuing active surveillance strategies.

- **Malaria mortality surveillance:** As stated in the **SM&E** chapter, monitoring changes in malaria-specific mortality is a challenge for malaria control programs. As programs approach elimination, accounting for deaths and confirming malaria infection will improve as all malaria cases are diagnostically confirmed and health information systems are strengthened. Malaria mortality data from routine surveillance will become increasingly accurate and reliable and malaria's contribution to ACCM estimates collected from surveys will decrease. Furthermore, malaria deaths should become increasingly rare in elimination settings.
- **Active surveillance:** Active surveillance includes efforts to seek out additional cases of a specific disease and can take several forms. It can include community health workers or health workers visiting villages and going door to door looking for people with signs and symptoms of malaria or testing all residents regardless of symptoms. Active surveillance is very resource- and time-intensive and is generally not considered until countries have a strong passive surveillance system and reach the elimination phase, when cases are few and health system capacity and resources allow. Active surveillance can be used in the elimination setting in several ways:
  - Identification of areas of high transmission or high-risk populations – case or infection finding among high-risk groups where higher prevalence or outbreaks might be expected based on historical epidemiologic, vector, meteorological, and/or migration data.
  - Transit programs to screen high-risk individuals for malaria when entering the country or low-prevalence areas within a country.

The effectiveness of active case detection in reducing disease burden remains unclear and such strategies should be carefully considered before they are implemented. Given the limited sensitivity of conventional RDTs and microscopy, especially in low-prevalence settings, teams need to balance the costs and potential benefits of this type of approach. Alternative approaches such as MDA are being evaluated as a strategy to reduce and interrupt transmission. See **Other Preventive Approaches** chapter (*'MSaT'* and *'MDA'* sections) for more detail. In addition, it is strongly advised that if active case detection activities are being considered, this should be done in consultation with the PMI Elimination Working Group and will generally be required to first be piloted as an OR study, assuming other evidence of effectiveness is unavailable, so that its effectiveness can be assessed.

- **Reactive case detection:** Elimination countries with robust health systems and capacity to investigate cases may employ various surveillance methods that combine passive and active surveillance. Case notification, investigation, and response efforts, such as China’s “1-3-7”<sup>183</sup> approach, fit in the category of reactive case detection. Cases are first identified by passive surveillance and reported within one day. A case investigation is completed within three days of notification, which includes both geolocating the case’s residence and collecting personal, household, and environmental information that helps determine whether the case was likely to be locally-transmitted or imported. Further action is taken within seven days which often includes reactive case finding in a predefined radius around the identified case where the patient lives or works and treatment of additional confirmed cases.

Most countries targeting malaria elimination conduct some sort of reactive case detection activities. However, countries vary greatly in what triggers response measures, what diagnostic tests, if any, are used to identify additional cases and infections, whether testing is performed on asymptomatic persons or only symptomatic, the targeted radii, and the additional vector control and community education activities conducted in response. Countries use a wide range of response radii from the index household to up to 3km, often dictated by operational feasibility. Increasing evidence suggests that if local transmission is occurring, the likelihood of finding additional cases is highest in the index household and decreases rapidly beyond 200m from the index household. Determining the optimal radius for the area for case-finding activities should also be balanced by what is operationally feasible in the particular setting and by factors, such as housing density and topography.

### *Draft PMI Elimination Indicators*

In order to track progress towards elimination, the following indicators are recommended for countries embarking on elimination:

- Annual Parasite Index
- Test Positivity Rate
- 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)
- Villages with access to community-level case management
- Proportion of expected public health facility and community provider reports received
- Proportion of expected private health facility reports received
- Annual blood examination rate

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<sup>183</sup> Cao J, Sturrock HJW, Cotter C, Zhou S, Zhou H, Liu Y, et al. (2014) Communicating and Monitoring Surveillance and Response Activities for Malaria Elimination: China's “1-3-7” Strategy. PLoS Med 11(5): e1001642. doi:10.1371/journal.pmed.1001642

- Proportion of 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 quarterly reporting.

## Social and Behavior Change (SBC)

In areas with high, moderate, low, and very low transmission alike, use and uptake of malaria interventions rely heavily on community awareness, demand, and acceptance of essential commodities and services. As such, SBC can play an integral role in malaria elimination. 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, behavior maintenance will also become more important particularly with regard to ITN use. Although there is no “one size fits all” approach for specific strategies and channels that should be used for SBC in elimination settings, key aspects of behavior change should be considered (please refer to the SBC Guidance for a description of approaches supported by PMI across all transmission settings).

### *Vector control*

Two of PMI’s main interventions – insecticide-treated mosquito nets (ITNs) and indoor residual spraying (IRS) – are aimed at controlling mosquito populations and are especially important in sub-Saharan Africa where nocturnal indoor-biting and resting behaviors are common. While these interventions are highly effective, the gains may be quickly reversed if net use or IRS acceptance falls. As such, the transient adoption of a behavior is not enough, particularly in an elimination setting; consistent use of ITNs and acceptance of IRS must be maintained at high levels.

While behavior maintenance for ITN use and acceptance of IRS is important in areas transitioning to low, very low and zero transmission, additional considerations should be made. For example, establishing or reinforcing net use in fixed or sedentary communities may function differently than in smaller, mobile, migrant and vulnerable populations. In these settings, monitoring shifts in human attitudes, perceptions and behaviors will be important. To better understand behavioral influences and barriers in these settings, formative assessments using new surveys and sampling techniques may also be required.

## *Case management*

A key component of SBC for malaria case management is increasing treatment seeking behaviors especially through the public sector. In all transmission settings, SBC for case management at the community level should focus on establishing trust in the malaria test result and raising awareness of the broad spectrum of fever causes. It is equally important that SBC targeted at service providers focus on increased awareness of the broad spectrum of fever causes, emphasize adherence to national case management guidelines (for diagnosis and treatment) and improved communication for patients who do not receive treatment for malaria when presented with a negative RDT.

## *Malaria in pregnancy*

At the community level, SBC should encourage consistent ITN use, ANC attendance, prompt testing and treatment seeking for fever, and promote the uptake of IPTp, when appropriate. Activities that target service providers should continue to encourage provider adherence to national guidelines for IPTp dosing (timing and frequency) and malaria case management.

## *Surveillance, monitoring, and evaluation*

As countries shift to lower transmission and improve SM&E activities to capture robust data, special considerations to collect behavioral data on a routine basis should be made. For example, as active case detection is employed in low, very low and zero transmission areas, behavioral components could be incorporated into investigations to further understand and measure the uptake of the relevant behaviors as well as related behavioral factors. Refer to the Malaria Social and Behavior Change Communication Indicator Reference Guide, Second Edition, for indicators that can be adapted for elimination settings.

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 team for access to this learning.

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# DATA INTEGRATION

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

PMI leadership named “advancing PMI’s analytic capabilities” in order to optimize data-driven decision-making as the highest priority for the Initiative.

PMI has also established a new **Quarterly Report** activity, wherein partner countries are requested to report malaria-related health data, disaggregated by month and by district, on a quarterly basis.

**PMI Data Lake** serves as a new repository to ingest, house, analyze, and visualize data (supply chain, financial, entomological, demographic, climate, etc.) from various sources, including the data reported from countries on a quarterly basis

PMI is working closely with partners including the Global Fund and the Bill and Melinda Gates Foundation towards the shared goal of optimizing data-driven decision-making. The collaboration consists of four Workstreams, including: 1) Country demonstration Pilots; 2) Establishing Integrated Data Systems and Platforms; 3) Scaling Next-Generation/Innovative Surveillance Systems; and 4) Accelerating Introduction of New Tools.

PMI countries in SS Africa are now required to hire one additional PMI team member - a Malaria Data Specialist - to ensure PMI programs are appropriately staffed to support the new data- related priorities. This is not a requirement at present time for the smaller programs in Asia.

## **Introduction**

In 2018, newly appointed PMI leadership decided to place “advancing PMI’s analytic capabilities” as the highest priority for the Initiative. This new priority builds on more than a decade of extensive use of data for decision-making and impact-monitoring across USAID and CDC, and within PMI partner countries.

To spearhead this effort, PMI Headquarters established a new PMI Data Integration Team to work closely with both in-country and headquarters staff and partners to systematically link our different datasets and establish key questions for analysis. The PMI Data Integration Team is not focused on collecting more data, but instead on supporting more systematic, frequent, and

strategic use of what we already have, including exploring what useful data insights we can push to field staff end users.

As part of a new PMI Quarterly Reporting requirement, PMI partner countries are requested to share monthly district-level malaria-related health data on a quarterly basis. The goal of this quarterly reporting process is to better support NMCPs through more regular use of data for decision-making and to better monitor the impact of U.S. government investments in malaria control interventions (see Frequently Asked Questions at the end of this section for more details on the Quarterly Report process).

## Background

After experiencing a period of unprecedented improvements in malaria control, progress recently appears to have stalled--with several countries reporting alarming increases in malaria cases, including eight countries that witnessed an estimated increase in malaria deaths of more than 20% compared with 2015. Perhaps even more concerning than the increases in cases, is the fact that neither countries nor the broader malaria community knows whether the plateauing is due to reduced effectiveness and coverage of vector control interventions, increased rainfall or increased case reporting.

PMI, the Global Fund and other development partners have been supporting ministries of health (MOH) in the collection and reporting of national malaria-related data, such as service delivery data from the HMIS, supply chain data, entomological monitoring data, as well as financial, climate, demographic, behavioral, and intervention coverage data from population-based surveys such as MIS and DHS.

At both country and global levels, this massive amount of data is generally **fragmented** and disparate, which makes the production of insightful analytics to inform decision-making an unnecessarily time consuming process. MOHs and PMI country teams often do not have the resources to make sense of siloed datasets.

At the Headquarters level, the various malaria-related and program data is maintained from the 27 PMI focus countries in separate spreadsheets and **siloed** databases that do not exchange information. Data collection, reporting, and **triangulation** is **cumbersome** and **labor-intensive**. Given the sheer scale and complexity of the \$700 million PMI program, the Initiative's currently limited ability to learn iteratively from the triangulation of existing, routine malaria related data presents a significant management risk.

At the country level, the gradual transition from paper paper-based to digital health information systems (HIS) means more data can be used to inform decision-making. In addition to the widespread adoption of software such as DHIS2, for reporting malaria cases, countries have also

prioritized investments in other HIS sub-systems such as eLMIS. At PMI Headquarters, by recently standardizing and geographically disaggregating the way we plan funding levels by key intervention, we have also started making programmatic data easier to analyze.

## Goal and Vision for Data Integration

Goal: Integrating more advanced data analytics into PMI's business operations by accelerating processes for data utilization, sharing and integration across multiple, currently siloed data sources (from global and country programs and partners)---shortening the data-to-action cycle.

Vision: Granular data from key sources (from global and country programs and partners) flowing regularly into an open digital environment and are systematically used to inform decisions on resource allocation as well as to track progress.

## Additional Staffing Requirements on PMI Country Teams

To ensure PMI programs are appropriately staffed to support the new data related priorities, including the new quarterly report, missions in SS Africa are now required to hire a Malaria Data Specialist using the standard position description template. The role of the new Malaria Data Specialist will be primarily focused on boosting PMI's data management, visualization, reporting and use efforts outlined in the PD. This new FSN position will be 100% funded from each country's Malaria Operational Plan budgets. This requirement will be communicated by the Coordinator to Mission leadership. Missions that have constraints to immediately follow through on this requirement should discuss with the PMI leadership team.

## Special Data-Focused initiative with Global Fund and Gates Foundation

To optimize data-driven decision-making, PMI leadership and the Data Integration team is working closely with partners at the Global Fund and Bill and Melinda Gates Foundation along four workstreams:

- **Workstream A** - Country Demonstration Pilots: This workstream seeks to demonstrate the potential impact and efficiency gains of intensifying in-country investments for data-driven strategic decision-making and execution in two pilot countries (Burkina Faso and Benin).
- **Workstream B** - Establishing Integrated Data Systems and Platforms: To inform PMI, the Global Fund, and country program planning and execution, this workstream aims to build a web-based data platform that will, for the first time, house and integrate multiple streams of data (including supply chain, commodity, and financial data) from across all partner countries and donor programs in a single place. Through harmonization of PMI

and Global Fund financial and supply chain data, and updating malaria investment information, countries will be better equipped for planning activities.

- **Workstream C** - Scaling Next-Generation/Innovative Surveillance Systems. This workstream seeks to scale-up collection and use of entomological data; Demo use cases of genetic epi in high transmission settings and testing and support scale-up; and ANC surveillance, as applicable.
- **Workstream D** - Accelerating Introduction of New Tools: This workstream aims to ensure access to, sustainable markets for, and efficient scale-up of new and existing tools by articulating a clear pathway for prequalification and policy recommendation, driving reform on policy processes, and coordinating approaches to piloting and implementation of new tools.

## Quarterly Report Process - Frequently Asked Questions

### 1. What is the purpose of the PMI Quarterly Report?

PMI has decided to implement a Quarterly Report in order to strengthen its data-driven approach within individual countries and across multiple countries and help shorten the data-to-action cycle. The immediate aim is to increase PMI accountability and stewardship of US Government funds. However, the purpose of the PMI Quarterly Report (QR) is multi-pronged:

- 1) *Track progress of implementing partners.* The quarterly report will involve an effort to standardize indicators reported by implementing partners for each technical area and benchmarking programmatic results. Because US foreign assistance budgets are under ever-increasing scrutiny, PMI needs to improve our capacity to track progress and setbacks and demonstrate that we can address all issues in a timely fashion.
- 2) *Monitor trends and learn across regions.* PMI believes that the timely evaluation of change within a country and the ability to sum across countries will increase our accountability and stewardship of US Government funds.
- 3) *Amplify and build on existing systematic data reporting and analytical efforts.* Many countries are already implementing either monthly or quarterly reports (e.g. monthly bulletins). For such countries, PMI would like to augment in-country efforts by integrating data that they can use (such as survey and funding data) to triangulate with the data they typically use for their reports. For countries that do not currently systematically analyze their data, the analytical output of the QR can serve that purpose.

2. **Who is the audience?** Since the immediate aim is to increase PMI accountability and stewardship of US Government funds, the primary audience for this Quarterly Report is PMI. However, as we continue to learn with countries and improve the way we integrate and visualize data submitted through the Quarterly Report, there will be multiple audiences



including NMCPs and PMI, and in the long-term, if MOHs agree to share findings with the broader community, local stakeholders, and development partners.

**3. Who will have access to the data?**

PMI takes data security and ownership very seriously. Data submitted by countries will not be shared outside of PMI without the approval of the host country governments. These data will be combined with data that is housed at PMI-HQ or available publicly (i.e. PMI financial data, PMI-procured commodities, DHIS, MIS) to develop the reports. NMCPs will also have access to the underlying raw datasets behind QR dashboards for their respective country.

**4. How will analytical outputs produced by PMI HQ be shared with countries?** The visualization tool used for the QR analytical output will be via interactive Tableau dashboards --- housed on the [PMI data lake platform](#). NMCPs will be able to directly access these QR dashboards together with the underlying raw datasets via the PMI- supported data lake platform.

**5. Is PMI rolling out a parallel data reporting system?** No. PMI is requesting NMCPs to share data from existing deliberately not creating a parallel system to collect data at decentralized levels. Most countries already have their own data reporting systems (often DHIS2) and is not asking countries to collect those data in a new manner or to collect additional data elements that enable data flow from facilities to districts to central levels. As much as possible, countries should use their own national reporting systems to extract data to produce the PMI Quarterly Report. These data do not need to be entered into the PMI Quarterly Report template; the template is intended to serve primarily as a tool for outlining which data and levels of disaggregation are desired, and secondarily, for countries unable to extract the data directly from their HMIS, as a template to be filled out. For example, the MOH's national DHIS2 instance can and should be used to generate a report containing the requested data on malaria cases and deaths disaggregated by district and by month, and the in-country PMI team can submit this same report to PMI HQ for the quarter. The MS Excel PMI Quarterly Report data entry template is meant to serve as a tool to be completed at the central level --- only if other tools cannot be used to generate reports disaggregated by district. The PMI Quarterly Report data entry template is not meant for district health officers to report their data.

**6. What types of capacity building efforts will accompany the QR?** PMI will continue to support MOH and NMCP efforts to strengthen data reporting systems (e.g., HMIS, LMIS, entomological monitoring). PMI continues to explore ways to improve capacity.

**7. What approach should countries use to gather the QR data for submission to HQ?** In-country PMI teams are strongly encouraged to work closely with their NMCP counterparts

and, wherever applicable, other relevant MOH departments (e.g., HMIS unit or Central Medical Stores) to generate reports with the required data elements. In addition, in most countries, PMI is funding M&E and supply chain advisors through its various implementing partners, and these individuals can be tremendously helpful in helping to generate the required reports. Ideally, the person most familiar with the national HMIS or LMIS database would play a role in generating the report.

8. **Once the data are submitted to HQ, who is producing the QR?** PMI HQ will be responsible for reviewing the data submitted and producing the data visualizations for the Quarterly Report. Additional data will be provided from HQ levels (e.g. financial, climate, procurement and supply chain) for these visualizations, which we are continuously working to improve by incorporating more data sources and listening to your feedback. Working closely with their NMCP counterparts, it is anticipated that PMI in-country teams and NMCPs will also have a role in providing feedback into the analytical frame and in interpreting results from the analysis.
9. **What data use processes will be supported at HQ and country levels?** Collecting data from countries and even creating dashboards does NOT inherently result in better data use for decision-making. Through the QR process, organizational processes must be put in place to ensure data received from countries are analyzed and discussed with country teams, and that insightful feedback via QR dashboards are provided to countries --- with a recognition that appropriate analytical interpretation can only be performed by individuals who work in the nearest proximity to where the data originated for decision-making. At country levels, PMI will continue to support monthly or quarterly data review meetings at national and district levels.
10. **The new QR requirement will necessitate that PMI staff at country and HQ levels spend additional time on data gathering, cleaning, analysis, interpretation and acting on findings. Will this new Quarterly Reporting effort be met with additional financial and human resources?** PMI senior leadership is exploring the feasibility of negotiating with Missions the hiring of additional FSN staff to join in-country PMI teams to support this new effort. PMI is also investing in a data warehousing and analytics platform to automate some of the data ingestion, integration and visualization processes required by the new QR.
11. **Why not implement semi-annual reports?** Most of the countries we work in have highly seasonal malaria transmission. There are at least four times a year when we should explore, based on available data, whether PMI should be making changes or stay the course because there were no changes from previous years. Implementing quarterly reports allows PMI to become more responsive to changing situations in the countries it supports.

- 12. Why are we asking for sub-national data (district level of disaggregation)?** In most countries, there is great variability in how malaria occurs geographically. Collecting geographically-disaggregated data will allow for more focused analysis and better allocation of resources. Moreover, PMI increasingly needs to become better at tracking the performance of PMI-supported country programs.
- 13. Are we asking for results for both PMI-supported and non-PMI-supported programmatic results?** In this initial pilot phase, for programmatic results, the focus of the Quarterly Report will be on PMI-supported programmatic results only (e.g., “ITN campaign implemented during the quarter” under the Programmatic Data tab). However, it is anticipated that HQ will soon begin also requiring results from activities supported by other partners since PMI needs to get a better, more comprehensive picture of what is happening in order to know if its investments are adequately distributed.
- 14. Do we run the risk of taking power away from NMCPs by collecting this data?** PMI’s primary purpose is to strengthen national malaria control programs. By working together closely on collecting and analyzing the data for the Quarterly Report, PMI intends to build on NMCPs existing efforts to improve data-driven decision-making and strengthen national malaria surveillance. To further inform national efforts, PMI HQ also intends to complement existing datasets available in-country with some of its other data sources (e.g., population-based survey MIS and DHS, funding levels by district, commodity procurements, IRS and insecticide resistance data from centrally-funded implementing partners) as well as providing insights into what is happening in neighboring countries. PMI intends to facilitate NMCPs' existing efforts to use data to make decisions by integrating data sets that previously have been difficult to synthesize (e.g., population-based survey MIS and DHS, funding levels by district, commodity procurements, IRS and insecticide resistance data from centrally-funded implementing partners). NMCPs can use these integrated data sets and visualizations in the quarterly reports to inform their decisions.
- 15. If we believe data quality is poor and/or the monthly data has not been validated by the country, should we still submit to HQ? And will there be opportunities to re-submit validated data at a later stage?** Recognizing that countries continually make efforts to address data quality issues, PMI HQ still firmly believes that insights can be gained by systematically compiling and analyzing data. Local context will be used to interpret results from these analyses. Each quarter, countries will have an opportunity to provide updated datasets (even if these were previously submitted).