

PMI TECHNICAL GUIDANCE FOR FY 2021

Addendum to FY2020 Full Guidance

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VECTOR MONITORING AND CONTROL

Larval Source Management

Larval Source Management (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 public health intervention, unless conducted with a high degree of rigor, is inadequate. Thus LSM is recommended by WHO as a supplemental intervention to either ITNs or IRS in those settings where larval habitats are “few, fixed, and findable.”¹ LSM is only indicated when coverage and quality of ITNs or IRS is high, but malaria transmission remains.²

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

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

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

¹ https://www.who.int/malaria/publications/atoz/interim_position_statement_larviciding_sub_saharan_africa.pdf

² <https://www.who.int/malaria/publications/atoz/9789241550499/en/>

- (1) **LSM implementation in low transmission settings:** PMI funding may be used to support LSM in the context of elimination in areas where larval habitats can be efficiently located, where good coverage and quality of either ITNs or IRS is in place, and it is coupled with high quality case management and case investigation in transmission foci.
- (2) **LSM OR/PE in higher transmission settings:** To support focus countries that are moving forward with non-PMI funded large-scale or even nationwide implementation of LSM in accordance with specific national directives, PMI funding may be used to support HQ reviewed and approved Operational Research (OR) or Program Evaluation (PE) to assess the effectiveness of LSM in combination with other interventions, and to generate the evidence needed to develop more comprehensive guidance on LSM.

Please consult with your PMI VMCT backstops for guidance on implementation of LSM in elimination context or development of any LSM-related OR or PE in higher transmission settings.

ENTOMOLOGICAL MONITORING

Maintenance and Characterization of Mosquito Colonies

Susceptible colonies of mosquitoes are used for the assessment of ITNs, quality control of IRS, and verification of treated papers for WHO susceptibility tests and CDC bottle bioassays. In order to ensure that the colonies have not been contaminated by selection in the insectary, wild mosquitoes kept in the insectary, or wild mosquitoes entering the insectary, the colonies should be tested regularly. The tests should include a bioassay with the insecticides for which the susceptible strain is used (i.e., if the strain is being used for monitoring Actellic IRS, then the strain should be bioassayed with pirimiphos methyl, if it is being used for testing standard ITNs, a pyrethroid insecticide should be used). Additional molecular confirmation of the strain can be done by testing the strain for common resistance mechanisms (i.e., *kdr*, related to DDT and pyrethroid resistance, or *ace1^R*, related to organophosphate and carbamate resistance). Alternative bioassays may be useful for other strains, such as the *CYP6p9a_R* mutation in *Anopheles funestus*. However, the key characterization that should be done is a phenotypic resistance test (WHO susceptibility test or CDC bottle bioassay), and these should be done quarterly.

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

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

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

Human Landing Catches

Alternatives to Human Landing Catches. In some countries, there are objections to the use of human collectors as is commonly done in Human Landing Catches (HLCs). These objections are usually based on the idea of increased exposure for collectors to malaria and other vector-borne diseases. Research has shown that HLC collectors on chemoprophylaxis (as recommended) were at considerably less risk of malaria than the surrounding population. Still, there are other vector-borne diseases that HLC collectors may be exposed to, including lymphatic filariasis, leishmaniasis, o'nyong-nyong, etc. Additionally, if collections extend into the daylight hours, there may be increased risk of *Aedes*-borne viruses (dengue, chikungunya, and yellow fever). Nonetheless, it is not known if there is an elevated risk to mosquito collectors during HLCs. At present, PMI guidance is that HLCs may continue, if supported by national ethics committees and National Malaria Control Programs. Should evidence emerge that collectors are at increased risk compared to non-collectors, this guidance will be revised.

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

For additional information on alternative collection methods, please contact your respective PMI VMCT backstops.

INSECTICIDE-TREATED NETS

Durability Monitoring

ITN durability monitoring measures the effect of normal daily use on: *attrition* [as measured by the loss of nets for *any reason* as well as *due to wear and tear* from households]; *physical durability* [as measured by the number and size of holes in the net]; and *insecticide effectiveness*, [as measured by bioassay, tunnel test, and chemical content analysis, depending on type of net]. Final results of durability monitoring (upon completion of 36-month report) are made publicly available via pmi.gov, www.durabilitymonitoring.org.

In general, PMI will not support durability monitoring of products for which data have already been collected in-country. PMI funding may only be used to support DM in the following circumstances:

- In countries that have never implemented durability monitoring (and large countries with expected differences due to ecological, social, etc. differences).
- In countries that have implemented durability monitoring and where significant issues with ITN durability have been identified.
- To monitor new types of nets (e.g., PBO or dual AI ITNs). While there is little reason to believe that the physical durability of nets with new active ingredients will be different than that of standard nets in the same context, understanding how long the active ingredients are effective on these nets is important. For these new types of nets, it will most likely suffice to monitor chemical and bioassay aspects (see below).

“ITN Bioefficacy Monitoring.” In countries that have previously conducted durability monitoring and are deploying new types of nets, PMI does not recommend another round of durability monitoring, but rather monitoring of insecticide effectiveness (i.e., bioassays and chemical testing). This approach would not include monitoring of attrition or physical durability (i.e., hole counting) or the full questionnaire. The activity should include, at a minimum:

- Data collection at two sites
- Collection of 30 nets per site, per timepoint (baseline, 12, 24, 36 months) for bioassays and chemical testing
- Streamlined questionnaire [template to come]

Chemical testing should be conducted at CDC or another qualified laboratory. If analysis of insecticidal content is to be done at CDC, engage your respective country entomology backstop.

Please consult with the PMI VMCT for further details.

ITN Procurement and Distribution

ITN Product Selection. Current [PMI policy](#) requires that ITN products, at minimum, be on the WHO [Prequalification \(PQ\) list of Prequalified Vector Control Products](#) to be eligible for PMI procurements. PMI also reserves the right to apply additional criteria related to label claims, past performance, financial viability and programmatic consistency to qualify ITN products for PMI procurements. Furthermore, for those ITN products that have been deemed to be “equivalent” through the PQ conversion process, PMI specifically requires that they have a PQ listing and have demonstrated field effectiveness according to label claims (e.g., against resistant mosquitoes). The PMI VMCT will review evidence pertaining to non-inferiority (blood-feeding and mortality indicator) to inform PMI procurement policies.

Evidence Base for New Dual-AI Nets. The New Nets Project (NNP) has created a summary document of the existing data on dual-active ingredient nets as well as ongoing and upcoming evaluations in order to educate NMCPs participating in the NNP. For the Interceptor G2, hut trial results show that IG2 nets demonstrate improved efficacy and wash resistance compared to standard alpha-cypermethrin nets against pyrethroid resistant mosquitoes. Hut trials using Royal Guard have been conducted in Tanzania and Benin, demonstrating equal or superior performance in comparison to the reference DuraNet. Additional evidence is being collected through effectiveness pilot evaluations as part of NNP. The full document is available on the NNP [website](#).

Frequency of mass campaigns. In line with current Global Fund [guidance](#) that a *net life-span of 3 years should be assumed, unless local evidence justifies a longer or shorter interval*, if local evidence exists and the country demonstrates commitment to more frequent ITN campaigns through its resource prioritization, PMI can support campaigns more or less frequently than every three years. Nonetheless, while data in some places may demonstrate that ITNs are lasting less than three years, in general, it is likely not feasible from a resource perspective alone to change the cadence of mass distribution campaigns. Data could be used to bolster support for increased continuous distribution to complement mass distributions (e.g., bolstered ANC/EPI, introducing or expanding, school-based or community distribution, etc.). Countries interested in piloting new channels of distribution should contact the PMI VMCT.

Universal coverage with appropriate vector control interventions. Using data for decision making about when and where to deploy interventions is consistent with global guidance from WHO. As per the [October 2019 WHO Malaria Policy Advisory Committee \(MPAC\) meeting report](#), “Universal coverage for malaria vector control is defined as universal access to and use of appropriate interventions by populations at risk of malaria,” thus moving away from universal coverage with nets and focusing on universal coverage with the right interventions in the right place. PMI fully embraces this global guidance pivot.

ITN Social and behavior change (SBC)

Net care should continue to be a priority theme; having very positive attitudes toward net care has been shown to have a protective effect on ITN durability.³ PMI continues to promote guidance on net care and

³ See: [Impact of a behaviour change intervention on long-lasting insecticidal net care and repair behaviour and net condition in Nasarawa State, Nigeria](#) and [Impact of a behaviour change communication programme on net durability in eastern Uganda](#)

use (including reference to misuse and outdoor sleeping); see: [Social and Behavior Change for Insecticide-Treated Nets \(2019\)](#) document. Furthermore, SBC is particularly important for countries that are implementing multi-product campaigns. It should be emphasized that all nets being distributed are effective. Maps or other visual communication materials can facilitate understanding by non-technical audiences. Do not refer to certain nets as “better” or “next generation” which infers inferiority of other nets. For more detail, refer to [Planning and Operational Recommendations for Multi-Product ITN Campaigns](#).

INDOOR RESIDUAL SPRAYING

Special Considerations for the Deployment of Fludora Fusion for IRS. PMI VMCT does not believe it is necessary to restrict the use of Fludora Fusion in areas with deltamethrin resistance. However, it is not recommended that Fludora Fusion be co-deployed in areas where deltamethrin-containing (standard or PBO synergist) ITNs have recently been or will be distributed.

Selection and Implementation of Clothianidin Insecticides for IRS. It should be noted that SumiShield and Fludora Fusion both belong to the neonicotinoid class of insecticides, and thus switching between these two products does not constitute an insecticide rotation as described in the FY 2020 Technical Guidance. Please note the following guidance on the selection and rotation strategy of clothianidin insecticides for IRS:

- Unless there is local data showing clear differences in residual efficacy, acceptance, etc. that have the potential to reduce the impact of IRS, Fludora Fusion and SumiShield should both be deployed in a country’s IRS campaign each year to maintain market stability. For example, if a country’s IRM plan calls for an insecticide in the neonicotinoid class to be sprayed in a total of six districts in a particular year, SumiShield should be used in one half and Fludora Fusion in the other half.
- If country-specific data are currently available for only one or neither clothianidin product, it is recommended that both Fludora Fusion and SumiShield be procured and evaluated in separate districts a single spray campaign to determine any local differences in residual efficacy, acceptance, etc., which are critical to inform future procurements.

SEASONAL MALARIA CHEMOPREVENTION

WHO convened a consultative meeting in which the SMC guidelines and evidence for expansion of the current recommendations were reviewed.

- a. No changes to current eligibility criteria or implementation guidance were made
- b. Prioritization remains increasing effective coverage of the most vulnerable population (children 3-59 months)
- c. Once effective coverage of children 3-59 months has been achieved pilots exploring expansion of SMC could be considered in the following order:
 - i. Increased number of cycles
 - ii. Increased age range
 - iii. Increased geographic coverage

Directly Observed Therapy of day 2 and day 3 AQSP drug regimens is not recommended by PMI without clear evidence of low adherence.

AQSP for seasonal malaria chemoprevention. If SMC is relevant to your country team and PMI is requested to procure commodities, orders must be 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 Clerisse Lemke (clemke@usaid.gov) for supply chain questions specific to SMC.

CASE MANAGEMENT

World Health Organization (WHO) notification on the use of artesunate-pyronaridine for treatment of uncomplicated malaria. The WHO released a notification in October 2019 clarifying that artesunate-pyronaridine (AS-PYR) (brand name Pyramax) can be considered an efficacious and safe artemisinin-based combination therapy (ACT) for the treatment of uncomplicated malaria in adults and children weighing 5 kg and over in all malaria-endemic areas[1]. The notification was intended to clarify WHO’s recommendation of AS-PYR because it is not included in the current WHO Guidelines for the Treatment of Malaria (2015) but AS-PYR will be included in the next version of the WHO Guidelines for the Treatment of Malaria, which is expected to be released in late 2020. Additional information regarding selection of new antimalarials is contained below (“Updated PMI guidance on ACT selection” section) and in supplemental communication to the field.

WHO notification of prequalification of a second manufacturer of dihydroartemisinin-piperaquine. There are now two WHO-prequalified manufacturers of dihydroartemisinin-piperaquine (DP)[2]. Dihydroartemisinin-piperaquine produced by Alfasigma S.p.A. (brand name Eurartesim) was prequalified by WHO in October 2015 and added to the WHO Model List

of Essential Medicines in June 2017. It is available in two tablet formulations (20mg/160mg, 40mg/320mg), but it does not currently have a dispersible pediatric formulation.

Dihydroartemisinin-piperaquine produced by Guilin Pharmaceutical Company Ltd. (brand name D-ARTEPP™) was prequalified by World Health Organization (WHO) in November 2019, and it will be available in two tablet (40mg/320mg, 80mg/640mg) and two dispersible formulations (20mg/160mg, 40mg/320mg). Additional information regarding selection of new antimalarials is contained below (#3) and in supplemental communication to the field.

Updated PMI guidance on ACT selection. There are now six ACTs recommended by WHO as first-line treatment of uncomplicated malaria: artemether-lumefantrine (AL), artesunate-amodiaquine (AS-AQ), mefloquine-artesunate, sulfadoxine-pyrimethamine (SP)-artesunate, dihydroartemisinin-piperaquine (DP), and artesunate-pyronaridine (AS-PYR). All six ACTs are considered efficacious and safe. Most countries in Africa continue to rely on AL and AS-AQ as first- or second-line treatment options. Mefloquine-artesunate is recommended only for areas with multi-drug resistance (i.e., parts of Southeast Asia and South America). The use of SP-artesunate is limited primarily due to SP resistance. For more information on considerations for ACT selection including considerations for DP and AS-PYR, please refer to the forthcoming document titled “Updates on dihydroartemisinin-piperaquine and artesunate-pyronaridine and considerations for ACT selection in Africa” which will be shared in March 2020.

Although AL and AS-AQ remain efficacious in most countries in Africa, some situations warrant the introduction of the newer ACTs in addition to or instead of AL and AS-AQ. Because SP-AQ is used for seasonal malaria chemoprevention (SMC), AS-AQ is not recommended as a first or second-line treatment in countries or parts of countries that conduct SMC. Secondly, despite overall high efficacy of AL and AS-AQ in Africa, there are some instances where treatment efficacy appears to be waning. As the efficacy of any particular ACT begins to decline to between 90-95% in any country as measured by conducting a therapeutic efficacy study (TES), NMCPs, in collaboration with WHO, PMI, and other stakeholders, should proactively plan to update policies and change drug procurement to an alternate antimalarial(s). Consideration should be given to known resistance patterns in the country when selecting a different antimalarial.

Additional information regarding considerations in the selection of new antimalarials, including cost, evidence of resistance, formulations, and other treatment benefits will be included in a supplemental communication to the field. Any immediate questions can be directed to the PMI Headquarters Case Management Team Leads (Meera Venkatesan, mvenkatesan@usaid.gov; Eric Halsey, ycw8@cdc.gov).

Updated PMI guidance on funding and technical support for therapeutic efficacy studies in PMI-supported countries. PMI and the Global Fund support the majority of the therapeutic efficacy studies (TESs) in PMI-supported countries in sub-Saharan Africa. In collaboration with the NMCP, PMI is able to provide support through technical and support staff based in-country, technical experts and support staff based in the United States at USAID/Washington and CDC/Atlanta, and implementing partner staff, which allows for regular technical interactions with local investigators conducting TESs and helps to ensure the quality and timely sharing of the final product.

In order to leverage institutional capacities to the fullest, PMI and Global Fund leadership have agreed that PMI will now assume sole funding and technical responsibilities in PMI-supported African countries where Global Fund currently or formerly funded a TES. This transition will occur in conjunction with the Global Fund funding requests that are currently in development and it is expected to cause minimal disruption. This new TES funding arrangement will not impact WHO-funded TESs, which are currently implemented in a handful of PMI African countries. A joint letter from PMI and Global Fund outlining the changes has been shared with PMI teams.

Updated PMI guidance on the use of intermittent preventive treatment in infants. In 2010, WHO issued guidance on the use of SP for intermittent preventive treatment in infants (IPTi), which 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).

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

PMI countries can consider adding support for IPTi with SP, where eligible, according to WHO guidance. This addition would be in addition to and not replacing PMI's support for the core interventions, including nationwide scale up of quality case management, vector control, etc. To date, NMCPs in PMI-supported countries have not prioritized IPTi in any country except Sierra Leone.

Updated PMI guidance on the procurement of rectal artesunate. Rectal artesunate is recommended only for the pre-referral management of severe malaria in children aged 6 years or less. Children aged 6 years or less should receive a single rectal dose (10 mg/kg body weight)

and immediate referral. Because severe malaria is life-threatening medical emergency, WHO has recommended[3] that 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.

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

Reminder: Mass drug administration (MDA) and Artequick. Heads of State and/or Ministers of Finance in a number of countries in Africa have been approached by the Chinese government with offers of free Chinese produced malaria drugs for use in mass drug administration campaigns (MDA). Because the antimalarial being offered (Artequick, artemisinin-piperazine) has not been WHO-prequalified or approved by a stringent regulatory agency, WHO, PMI, and global partners including the Global Fund do not recommend its use for case management or for chemoprevention. PMI resources can not support any aspect of implementation of activities using non stringent regulatory approved drugs. Additionally, the use of MDA has clear WHO recommendations for use in limited, specific epidemiological contexts, and would not be appropriate in most PMI settings. Please refer to a communication to the field sent by email from the Meera Venkatesan on October 31, 2019.

Digital Community Health. Each PMI country program is required to contribute at least 0.75% of their overall budget to support the digital community health activity. (Please see November 22, 2019 email message from the PMI Coordinator). Specific instructions on mechanisms will be shared separately by leadership.

Case Management Resources

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

https://drive.google.com/drive/folders/1h5eiTRgCMc_18YAYpIUnR9GEfyaM0kUP?usp=sharing.

[1] World Health Organization. The use of artesunate-pyronaridine for the treatment of uncomplicated malaria. October 2019. <https://apps.who.int/iris/handle/10665/328762>

[2] WHO prequalification link: https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_ap

[i aggregation 1=&field medicine pq date%5Bdate%5D=&field medicine pq date 1%5Bdate%5D=&field therapeutic area=19&field medicine status=&field basis of listing=All](#)
[3] [Rectal artesunate for pre-referral treatment of severe malaria](#). WHO October 2017.

HEALTH SYSTEMS STRENGTHENING

Field Epidemiology Training Program (FETP)

Updated list of countries with current frontline programs. Benin and Cote D'Ivoire currently do not have a program. Niger is in the process of establishing one.

Updated the FY19 PMI supported list of FETP. As of FY 2019 planning, PMI is supporting FETP advanced program trainees in 13 countries: Angola, Burma, Cameroon, DRC, Ethiopia, Ghana, Kenya,, Mozambique, Nigeria, Rwanda, Tanzania, and Uganda, and Zambia. Due to the decentralization of the health system, PMI is supporting the FETP intermediate program in Burkina Faso.

Regional advanced program in Burkina Faso. In addition, countries may consider sending trainees to the regional advanced FETP program in Burkina Faso. Trainees will do the didactic portion of the training in Burkina Faso and then return to their respective countries for the practical experience with mentorship provided by leaders in their home countries. In January 2020, cohort 5 was launched with residents from: Mauritania (8), Niger (8) , Mali (5) and Guinea Bissau (3). Cohort 6 will be launched in April 2020 with residents from: Benin (3) Burkina (4), Côte d'Ivoire (4), Guinea (6), Senegal (3) and Togo (3). Where appropriate, countries may choose to support residents participating in the regional program or even if not supported by PMI, link these residents with PMI and the NMCPs for malaria specific field experiences, SM&E and mentorship.

SOCIAL AND BEHAVIOR CHANGE

Formative Assessments on Barriers and Facilitators

Designing SBC activities requires an 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 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 Health Communication Capacity Collaborative (HC3) and Breakthrough ACTION in collaboration with the SBC 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. 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 and behavioral factors programs should prioritize. *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 ideal time to plan for and implement the MBS may include: periodic national strategy revision; a reorientation or shift in national goals; stagnation or lack of progress in uptake of malaria behaviors; the design phase of a new large-scale project; and/or any other transition point where behavioral data are needed to guide programmatic decision making, whether at the formative, implementation, or evaluative program stage. The decision to conduct an MBS, including the timing and scope, should be negotiated with the NMCP in coordination with the PMI SBC and SME teams with the following factors in mind:
 - **Timing:** From initial discussions to dissemination of the final report, it takes just over a year to complete an MBS, and data collection needs to take place during high

transmission months. Additionally, the SBC Team recommends the MBS not be conducted in the same year as an MIS or DHS. Ideally, an MIS/DHS and MBS should be conducted a minimum of eighteen months apart. See below for additional information.

- **Scope:** Final decisions about the scope of an MBS will often be guided by budgetary limitations. For countries interested in implementing a nationwide MBS, the SBC Team recommends a sampling approach that provides estimates based on the major malaria transmission zones of the country, where important differences in behavioral determinants may exist. Other sampling approaches could include a focus on PMI target areas or geographic zones of programmatic interest. In order to maximize MBS coverage, co-financing with other donors may be an option. The MBS is *not designed to provide intervention coverage estimates*.
- **Low-Transmission Settings:** The SBC Team is working with Breakthrough ACTION to develop a questionnaire and implementation guidance that is tailored to low-transmission settings. The adapted questionnaire, which will be reviewed by the PMI Elimination Team, is intended to assess how behavioral determinants like risk perception may shift in areas with low transmission. Thus, it will be tailored to assess behaviors related to interventions implemented in low-transmission settings (e.g., active case detection, screening of travelers to and from high burden areas, etc.). This adapted questionnaire will be piloted in 2021. As activities funded in the FY2021 MOP will not be implemented until CY2022, this should not be an issue and countries with low-transmission settings are encouraged to plan for an MBS.

The MBS is implemented through Breakthrough ACTION and country teams should consult the SBC Team to discuss sampling options, budgeting, and additional planning for an MBS. Additional information about the MBS can be found in the [MBS Overview](#) and the [MBS Implementation Guidelines](#).

- **SBC Module for the MIS:** The RBM SBC Working Group developed an optional standard module of malaria SBC-related questions that were approved by the DHS Program in August 2019. While the MIS currently measures some behavioral outcomes and determinants, this information is insufficient for assessing factors beyond knowledge. This standard module helps ensure that SBC questions included in the MIS are standardized, grounded in behavioral science, and backed by evidence so that the indicators can be used to help countries identify: (1) which populations/areas need to be targeted, (2) which SBC approaches are likely to be most effective, and (3) what kinds of messages should be promoted to facilitate behavior change. Additionally, this module helps those at the country-level compare results with countries sharing similar transmission patterns or development

contexts and facilitates the use of data for SBC program implementation. The optional module contains nine priority indicators:

1. Percentage of women age 15-49 who have seen or heard a malaria message in the past six months
2. Among women age 15-49 who have seen or heard a malaria message in the past six months, percentages who cite specific sources for malaria messages
3. Percentage of women age 15-49 who state there are ways to avoid getting malaria
4. Among women age 15-49 who state there are ways to avoid getting malaria, percentages reporting specific ways to avoid getting malaria
5. Percentage of women 15-49 who perceive they are at risk from malaria
6. Percentage of women age 15-49 who feel that the consequences of malaria are serious
7. Percentage of women age 15-49 who are confident in their ability perform specific malaria-related behaviors
8. Percentage of women age 15-49 who have a favorable attitude toward specific malaria-behaviors
9. Percentage of women age 15-49 that believe the majority of their community currently practice specific malaria malaria-related behaviors

The SBC Team strongly recommends that countries include the optional module in all upcoming MIS surveys. This standardized set of indicators should be the primary source of data about malaria SBC in MIS surveys. The inclusion of additional malaria SBC questions is not recommended as the data generated by unvalidated and non-standardized SBC questions has the tendency to go unanalyzed and unused.

Relationship between the MBS and the SBC Module for the MIS: The MBS, like the MIS, is a major data collection activity requiring country buy-in, budget support, and a skilled partner for implementation. An important factor to consider with the respect to the timing of the MBS is the timing of any upcoming MIS. Due to the intensive nature of these surveys, the PMI SBC and SME Teams recommends that an MIS and MBS *not* be implemented within the same year, and ideally, be conducted a minimum of eighteen months apart. Given the PMI SM&E Technical Team's current recommendation that an MIS be conducted every two or three years in high transmission settings and every five years in low transmission settings, the timing of the MBS, which is recommended in all settings every five years, must be carefully planned. Ultimately when deciding on the timing of an MBS, PMI Country Teams should consider the needs of the program, including needs for quality formative assessment or evaluative data to assess SBC programming to improve future implementation, as well as any other planned national-level household surveys. If countries need additional assistance determining the best time to field an MBS, they should contact the SBC and SME Teams.

DATA INTEGRATION

M-DIVE Platform and Digital Health

To optimize data-driven decision-making, PMI is developing a web-based Malaria Data Integration and Visualization for Eradication (M-DIVE) platform. The M-DIVE decision-support tool is designed to integrate previously siloed data, and automate the triangulation and analysis of relevant datasets, including epidemiological, supply chain, entomological, climate, demographic, programmatic, and financial data.

Since the M-DIVE platform is designed to be used at both global and country levels to facilitate more data-informed resource allocations, in support of NMCPs, each PMI country program is required to contribute at least 0.75% of their overall budget to support the development of the platform. (Please see November 22, 2019 email message from the PMI Coordinator).

Data-Specific Staffing Requirements on PMI Country Teams

To ensure PMI programs are appropriately staffed to support the new data related priorities, including the new Quarterly Report, missions in sub-Saharan Africa are required to hire a Malaria Data Specialist Foreign Service National (FSN) using the standard position description template. The role of the new Malaria Data Specialist will be primarily focused on boosting PMI's data management, visualization, reporting and use efforts as outlined in the PD. This new position will be 100% funded from each country's Malaria Operational Plan budget. This requirement has been communicated by the PMI Coordinator to Mission leadership (see October 22, 2019 message from the PMI Coordinator). Missions that have constraints to immediately follow through on this requirement should discuss with the PMI leadership team and are encouraged to contact Julie Wallace jwallace@usaid.gov to discuss a revised timeline for implementation of the requirement.

OPERATIONAL RESEARCH

MOP Submission

The description of any MOP-funded Operational Research (OR) or Program Evaluation (PE) in Table 2 must at a minimum include a clear OR/PE question, proposed evaluation design,

implications of either a positive or negative finding(s), proposed mechanism for implementing the study, and budget allocation.

Timeline for the Annual OR Prioritization

MOP Discussions (Mar-Apr)	Following MOP Submission (Q2)	OR Team Review (Q3)	Senior Leadership Review (Q4)	TBD
<p>Country teams discuss ideas and receive feedback from HQ backstop/ technical teams for MOP submission</p>	<p>Technical teams discuss and prioritize OR/PE ideas</p> <p>OR/PE ideas are submitted to the OR mgmt team</p>	<p>Pre-concept note (CN) idea vetting process for all core-funded OR/PE and MOP-funded OR:</p> <ul style="list-style-type: none"> • OR team reviews OR/PE ideas • OR team convenes a consultative meeting with PMI senior leadership and other stakeholders, as appropriate, to share and discuss top ideas. • Outputs of the meeting to include a consensus list of priority OR topics and budget allocation for Coordinator clearance 	<p>OR/PE prioritization process:</p> <ul style="list-style-type: none"> • PMI coordinator announces OR priorities and budget allocation • Approved ideas are invited to submit a CN • OR committee members are assigned to study to review and provide input • Deputy Coordinator provides technical oversight of CNs and adjudication, if needed 	<p>Approved CNs proceed to protocol development</p>

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- As country OR or PE proposals need to be submitted with their MOPs, country teams should consider setting aside sufficient time to discuss priorities to be funded as a team and with the NMCP during and possibly even before the annual MOP visits/ discussions.
- The annual OR/PE prioritization process applies to all core-funded OR and PE proposals as well as MOP-funded OR.
- Country-specific, MOP-funded PE proposals should be based on country priorities. These proposals should be submitted for research determination to assure that they have approval for moving forward as PE. Scientific rigor and the research determination plan will be reviewed by the OR committee through a concept note submission (see template below).

Distinguishing Operational Research (OR) & Program Evaluation (PE)

- PMI’s authorizing legislation, the Lantos-Hyde Act, defined OR as the “application of social science research methods, statistical analysis, and other appropriate scientific methods to judge, compare, and improve policies and program outcomes from the earliest stages of defining and designing programs through their development and implementation with the objective of the rapid dissemination of conclusions and concrete impact on programming.”^[1]
- The goal of the OR Management Team is to ensure all PMI-funded OR and PE are

conducted in a scientifically and ethically sound manner. To this extent starting with FY20 funding and newly reprogrammed funds, the OR Committee will review all concept notes for both OR and PE proposals (see template below). Full protocol review will be limited to all OR proposals (core and MOP- funded) and for PE core-funded proposals.

- In PMI, OR is distinguished from PE. The term “research” in OR indicates that the work has a primary intent of producing generalizable knowledge that can be applied across different settings and over time -- and the choice of the location and time of the study(s) is made on the basis of wider representativeness. In contrast, “program evaluation” has the primary intent of evaluating a specific set of activities to invoke improvements that can be applied to that local setting. While the findings from program evaluation can have relevance to other similar settings, the primary intent remains focused on the site and question being evaluated.
- In PMI, monitoring and evaluation (M&E) also have specific characteristics. Monitoring is defined as a continuous/repeated process used to track, understand, -- and ultimately improve or correct program actions as they are implemented. Evaluation is defined as a periodic activity to assess whether specific activities or interventions, or an entire operational program have reached their intended goals and have resulted in the desired outcome and/or impact. Evaluations can be non-research or research, depending on the intent of the activity. An evaluation is considered non-research when the purpose is to assess the success and challenges of an established program. An evaluation is considered research when the purpose is to test a new, modified, or previously untested intervention, service, or program, or when the purpose of the evaluation is to develop generalizable information that is applicable beyond the specific program being evaluated.^[2]
- Standardized surveillance and M&E/PE approaches that are repeated across countries (e.g., TES, MIS, DHS, entomological assessment tools, LLIN durability monitoring etc.) are routine and do not require OR committee review unless study components are added that would shift them towards research and thus require OR Committee review.
- With the recognition that PMI undertakes a broad spectrum of activities to inform and improve our programs from routine monitoring to OR, the table below provides general guiding principles for distinguishing routine monitoring (exempt from OR Committee review) from PE and OR.
- Please note that the ultimate review and decision of research vs. non-research can only be granted by an ethical review board. The study team’s plan for seeking human subjects review will be submitted in the concept note and initially assessed by the OR committee. The study team should also consult CDC Human Subjects to assess if the new “blanket” non-research determination for surveys and routine surveillance in place at the Malaria Branch at CDC might pertain to the proposed PE. Ultimately, the study team will be responsible for communicating to the OR Management team, the final research determination from an ethical review board. All studies that are determined ultimately to be research by an ethical review board will need to submit their protocol for review by the OR Committee even if they were initially assessed as PE.

	Monitoring	Program Evaluation	Operational Research
Definition	A continuous process used to track, understand, and correct activities and programs as they are implemented.	A periodic activity to assess whether specific activities or interventions, or an entire operational program have reached their intended goals and have resulted in the desired outcome and/or impact.	The application of social science research methods, statistical analysis, and other appropriate scientific methods to judge, compare, and improve policies and program outcomes from the earliest stages of defining and designing programs through their development and implementation with the objective of the rapid dissemination of conclusions and concrete impact on programming.
Purpose	To improve the performance or activities and programs (continuous).	To evaluate an established program with known/proven tools to inform the local setting.	To assess new tools or strategies to generate generalizable information to inform programs/policies.
Research/ Human Subjects Review?	No*	Yes/No	Yes
CN reviewed by OR Committee?	No	Yes	Yes
Protocol reviewed by OR Committee?	No	Core funded PE: Yes MOP funded PE: No, unless requested by the OR team during the CN review	Yes

*Although most routine monitoring activities do not undergo human subjects review, additional human subjects review is required for any CDC staff persons intending to publish these results. To this extent, CDC Malaria Branch has developed a “blanket” non-research determination protocol to help encompass these activities reducing the burden of submitting each activity separately. Please work with CDC DPDM Human Subjects and Annett Cotte as the point of contact on the OR Management Team to ensure all needed prior review is appropriately sought.

[Appendix: Concept Note Template for PMI Operational Research and Program Evaluation \(for both MOP or core-funded OR/PE\)](#)

[1] Lantos-Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act, 2008

[2] President’s Malaria Initiative Strategic Guidance for Operational Research, February 2014

COMMODITY PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

Supply Chain Strategy

Stock Outs Stop With Me: To achieve consistent and meaningful change in malaria commodity availability performance, PMI is taking a fundamentally new approach to optimizing PMI's supply chain investments, starting in CY 2020, that should influence the development of FY 2021 MOPs. PMI plans to operationalize a "Stock Outs Stop With Me" initiative with a program to guide PMI country investments towards achieving a clear, time-bound target for improved commodity availability at service delivery points. The program will establish the target to be used across PMI and develop a playbook, which will provide PMI country teams the assistance required to evaluate past investments and prioritize areas of future investments to reach the availability target. This program may begin to be implemented through revisions of current FY 20 implementing partner work plans and if not then certainly during the development of their FY 21 work plans. PMI country teams are requested to keep this program in mind when allocating funding across all PMI interventions during the development of the FY 2021 MOPs to ensure that PMI investments will address each country's most critical issue(s) impacting commodity availability.

Quantification

Gap Analysis Tables: Gap Tables for ITNs, SP, SMC, RDT, ACTs, Injectable Artesunate and Rectal Artesunate are required for MOP FY 2021 even if PMI funding may not be allocated towards the procurement of some of these commodities. If there is a proposal to have PMI fund the procurement of commodities other than these please include them in an additional tab.

PMI recognizes and appreciates the reasons behind there being considerable variation in the layout of MOP FY 2020 tables submitted across countries as the complexity of the quantification results are not easily conveyed using the few parameters provided in the blank gap analysis tables. For example, some countries used the number of posts/locations/facilities in addition to expected number of cases to calculate RAS need (rather than by % of severe malaria cases that will require a pre-referral dose). A blank table is not being provided for MOP FY 2021. Instead use the final version submitted in MOP FY 2020 as the starting point for the development of the tables for MOP FY 2021. This version will be made available through each countries' respective country folders. Please work with your country team, supply chain backstops, and supply chain implementing partners to update the tables. Note, only PMI can inform the tables regarding what will or will not be funded by PMI so do not rely principally on the supply chain partner to finalize the tables.

A quantification exercise is not required to update the tables, but any new information obtained should be reflected in the MOP FY 2021 tables. For example, the amounts carried over to the start of CY 2020.

For each tab related to a commodity type, add a column to the right of CY 2021 that will be for CY 2022 figures. For each commodity type, use the existing footnotes to inform the figures to be used in the CY 2021 column. Revise the footnotes as necessary, and wherever possible provide specific sources of data/assumptions rather than simply referencing the “National Quantification Report” as the data source.

Please remember to calculate for the amount of additional stock required to maintain country stock above minimum levels (i.e. avoid a stockout) under the needs for each CY and note where this has been factored into the figures presented, if it is not clearly identified with its own row in the worksheet.

Enter “Partner Contributions” according to the CY in which the products are expected to arrive rather than the year that they are procured.

Examples:

- If there is an ITN campaign planned for early CY 2022 and a partner’s contributions will arrive in CY 2021 then the quantity should be recorded under the CY 2021 column. Add a footnote explaining that the nets are for the 2022 campaign, otherwise it will look like an excess amount of nets in 2021.
- If there is an ITN campaign planned for late CY 2023 with a partner’s procurement initiated in CY 2022 but the ITNs arriving in CY 2023, then do not enter this in the column. Add a footnote with the amounts.

For the ITN table, please include a footnote with any information regarding the breakdown of quantities by type of net (Single Pyrethroid, PBO, Dual AI).

Commodity Procurement

Commodities Costing Table: In the commodities costing table, included separately with this addendum, the cost of commodities includes the costs of goods plus estimates on freight, insurance to port, clearance costs, and required quality assurance testing. The table is a subset of the commodities that PMI most commonly procures so please reach out to your supply chain backstop for a cost estimate if a commodity is not included that you plan to procure in your MOP.

Commodities Procurement Lead Time Table: 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. Please refer to the separate Average Lead Time Table included with this addendum for product specific lead times.

See Commodities Costing and Lead Time Tables in the Technical Guidance folder here: <https://drive.google.com/drive/u/0/folders/1PucmRzx7-wdDSbeScDLBRdy7kvxEcjf0>

Warehousing, Storage, and Distribution

Please contact Christie Hershey (chershey@usaid.gov) for more information on obtaining prior approval for the payment of service fees for warehousing and distribution.

PMI recognizes that the physical characteristics of ITNs and the uniqueness of their associated programming, in both routine and campaign distribution environments, often requires separate warehousing and transportation. PMI continues to fund the logistics for ITN warehousing and transportation but seeks, where feasible, to decrease the amount of funding allocated to the warehousing of campaign ITNs with MOP FY 2021 funding. Warehousing infrastructure is increasing in many of PMI's countries as is countries' ability to appropriately manage temporary storage of campaign nets. Countries teams are encouraged to work with their supply chain implementing partners to assess country capacity, and weigh the risk of country-managed warehousing (e.g. ability to safely secure the nets) and how to mitigate the risk. Based on the assessment, PMI should work with programs to help them identify sources of temporary warehousing for campaign ITNs and support them to manage these arrangements. This would be an investment in the recipient country's journey to self-reliance. Funding for in-country ITN distribution should be included as a separate line in the MOP (i.e. separate from ITN procurement and separate from distribution of other commodities).

Pending availability of additional data, storage of ITNs in containers for any length of time in-country is not recommended, given the potential risks of distributing ITNs that have become substandard as a result of exposure to high temperatures and/or humidity. No World Health Organization (WHO) pre-qualified (PQ) ITN supplier recommends storing their nets in containers. For more details, see: [Recommendations on the Use of Containers for the Transport and Storage of ITNs](#).

Quality Monitoring

PMI typically does not prioritize pharmacovigilance because of the well-established safety profiles of the antimalarials procured and distributed. As new antimalarials are introduced in PMI countries, requests for pharmacovigilance may increase. When considering pharmacovigilance as part of the introduction of a newer ACT, please contact the PMI Case Management and Supply Chain Management teams so that pharmacovigilance efforts may be coordinated with other donors and existing country systems and infrastructure.

Please contact Lisa Hare (lhare@usaid.gov) for concerns around any quality-related issues.

Monitoring and Supervision

End Use Verification (EUV): Costs for EUV should be included as a separate technical assistance line in the MOP, with the Proposed Activity listed as Pharmaceutical Management Systems Strengthening and the Description of Proposed Activity focused on the EUV.

Supply Chain Section of the Program Inventory: Additional elements have been added to the supply chain section of the program inventory but the criteria for each have been reduced from

what was included in the MOP FY 2020 technical guidance. Much of the elements and their associated criteria remain focused on the infrastructure, processes and management of the supply chain that malaria programs rely on rather than manage directly. Because of this and based on the experience of implementing the program inventory for the first time during the MOP FY 2020 exercise it is recommended that country teams work through the supply chain section first with their supply chain implementers and relevant country counterparts to prepare a draft of the inventory before forwarding this for the review of the malaria program and other stakeholders.