Malaria Information Note

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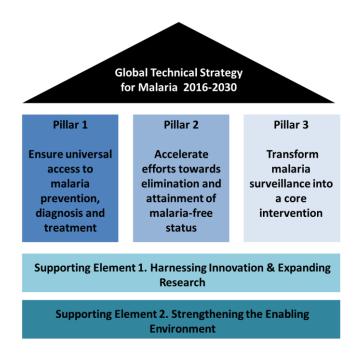
I. Introduction

This information note provides guidance to countries eligible to receive Global Fund financing for malaria on the formulation of a technically sound funding request. The document is in complete adherence with and complements normative technical guidance from the World Health Organization (WHO) and partner organizations. Each section has been written with a focus on Global Fund requirements and been kept as short and concise as possible, with a view to providing easy access to essential information. Details of importance to some readers may thus have been omitted. In addition, this document focuses mainly on interventions for the malaria control phase as countries in this phase receive the bulk of Global Fund support. Access to more detailed guidance is provided via links to key documents in the Key References section at the end of this Information Note. The document will be updated over the allocation period to incorporate new WHO guidance or other changes of importance to malaria programming.

General guidance on completing the Global Fund funding request (formerly referred to as "the concept note") is provided elsewhere, and should be consulted alongside this information note (link below).

The WHO's Global Technical Strategy for Malaria (GTS) lays out concrete targets for 2030 for all countries/regions based on three pillars and two supporting elements (Figure 1). To complement the GTS, Roll Back Malaria's (RBM) plan, Action and investment to defeat malaria 2016–2030 (AIM), ¹ builds a strong case for investment to mobilize collective action and resources for the fight against malaria.

Figure 1. Global Technical Strategy Framework - Pillars and Supporting Elements



Pillar 1 focuses on vector control, chemoprevention and case management as well as other vital malaria interventions. Pillar 2 is the political and structural backbone and encapsulates the strategic components required to enable programs to move towards elimination. Pillar 3 emphasizes the role of surveillance in assessing progress, allocating resources, advocacy and accountability, and targeting interventions to maximum effect and impact. The two supporting elements underscore the need for new tools and delivery methods, collaboration and coordination, government and partner commitment and sustainability.

The GTS lays out ambitious targets aligned with the timeframe of this funding cycle: by 2020, reduce malaria mortality and incidence by at least 40% compared to 2015 levels, and eliminate malaria in at least 10 countries with ongoing transmission as of 2015. Countries' National Malaria Strategic Plans, which operationalize the GTS goals and targets, are expected to be the foundation for countries' funding requests.

¹ Action and investment to defeat malaria 2016–2030 (AIM). Geneva, WHO. 2015 (http://www.rollbackmalaria.org/files/aim/RBM AIM Report A4 EN-Sept2015.pdf, accessed 2 May 2016).

II. Essential Background Information

To allow evaluation of the funding request within the country-specific context, applicants are required to provide essential background information. Below is a non-exhaustive list. The funding request should demonstrate how this information has been used for decision-making and strategic programming.

- 1) Summary of country context highlighting the epidemiology of malaria, including:
 - Parasite species present and their relative contribution towards burden;
 - Malaria burden, including description of epidemiological trends (incidence, prevalence, historical burden) and stratifications, geographic distribution of cases, as well as other relevant programmatic data (e.g. test positivity rate);
 - If relevant, details on vulnerable populations with barriers to accessing prevention and case management services including, but not limited to, human rights and gender-related barriers;
 - Description and proportions of different channels where people seek care (e.g. public, private, community, including traditional healers); proportion of population with access to diagnosis and treatment.
- 2) Past and current implementation, as well as lessons-learned:
 - Brief description of the health system including the community level;
 - Prevention and control implementation challenges encountered to date;
 - Current knowledge gaps;
 - Brief overview of current malaria interventions:
 - Diagnostic tool(s) in use and current testing coverage (e.g. testing rate);
 - First- and second-line antimalarial treatment; treatment for severe malaria;
 - Vector control tool(s) deployed and respective coverage and use;
 - Other core interventions e.g. intermittent preventive treatment in pregnancy (IPTp), seasonal malaria chemoprevention (SMC), etc.;
 - Monitoring and evaluation (M&E):
 - Date of last population-based survey (Demographic and Health Survey [DHS], Malaria Indicator Survey [MIS], Multiple Indicator Cluster Surveys [MICS]) and planned date(s) for upcoming survey(s);
 - Date of last therapeutic efficacy study, its findings and plans for future studies;
 - Date of last insecticide susceptibility study, its findings and plans for future studies;
 - Routine monitoring, including health interview surveys and malaria specific surveillance (particularly for countries approaching elimination);
 - Cross-border or regional activities/initiatives, as applicable.

As part of country dialogue, all relevant partners should be involved in the funding request discussions to ensure complementarity of efforts and alignment of data used for decision-making (e.g. quantification).

All countries should conduct a comprehensive gap analysis during the preparation of the funding request to help identify needs and gaps as well as prioritize activities (see RBM Country Regional Support Partners Committee (CRSPC – formerly the RBM Harmonization Working Group) gap analysis guidance and tool). Please ensure that the gap analysis submitted in the Global Fund funding request is consistent with the other gap analyses conducted in country.

The Global Fund encourages all countries to build sustainability considerations into their program design. In its new policy on <u>Sustainability, Transition and Co-financing</u>, the Global Fund outlines its principles for enhancing sustainability and provides a framework to support countries in transitioning successfully from Global Fund financing, which is differentiated along the development continuum. Additional information for applicants to develop funding requests in accordance with this policy can be found in the Sustainability, Transition and Co-financing Guidance Note (*forthcoming*).

III. Case Management

The key driver of reducing deaths to near zero is achieving universal access and adherence to diagnostic testing and treatment. Implementation of WHO's T3 (test, treat and track) initiative is underway in malaria endemic countries with varying degrees of scale up. However, improving and maintaining access and quality of care continue to be areas requiring attention.

While historically most countries have focused primarily on the public sector at the health facility level, community case management (integrated or malaria-only) has received increasing attention over the last decade. Limited – albeit also increasing – attention has been paid on increasing access and care in the private sector. Universal access requires a comprehensive approach to ensure quality case management in all sectors where people seek care. In their efforts to improve access and quality of care, countries therefore need to analyze the existing and potential contribution of each sector.

Most countries implement or are in the process of scaling up parenteral artesunate for severe malaria. Countries are encouraged to continue phasing out quinine for severe malaria, and improve pre-referral treatment and referral systems to ensure prompt treatment of severe cases. Please note that rectal artesunate has yet to receive WHO prequalification status, but the procurement of this product with Global Fund resources can now occur after approval is granted on a case by case basis.

Quantifying rapid diagnostic tests and artemisinin-based combination therapy

While multiyear quantification of diagnostic and treatment commodities is needed for a funding request, assumptions and needs should be reviewed annually when planning procurement. Quantification of these commodities can be based on program-generated consumption and/or morbidity data, and should factor in updated epidemiologic data and expected changes due to malaria intervention scale up.

Quantification estimations often include the whole potential population with suspected malaria (e.g. includes those that do not seek any care or those that seek care in the informal system). While these potential patients are part of the full need for testing and treatment in the country, they are not amenable to Global Fund support if there are no plans to cover them under a scale up plan.

For diagnostic commodities (e.g. microscopy or rapid diagnostic tests [RDTs]), quantification should be based on calculations of how many parasitological tests would need to be performed to evaluate all suspected malaria cases, whilst taking into account access to care (and in which sector if not all sectors perform diagnostic tests), parasitological testing coverage and reporting rates. The program would then need to estimate the proportion of tests to be performed by RDTs and/or by microscopy (using both national strategy targets and reported usage) and in which sector (public, private or community level) or geography. As RDTs and microscopy use in each sector differs, commodity needs should be calculated separately for each sector. In addition, selection of type of RDT (*Pf* only, PAN, etc.) should be based on the prevalent parasite species present, in accordance with WHO guidance.

For artemisinin-based combination therapy (ACTs), quantification should follow the estimates of parasitologically confirmed cases and those acute febrile illness treated as presumed malaria.

Adjustments should be made (increases or reductions) based on the following factors:

- Vector control coverage: Whilst the RBM CRSPC has recommended a 10%, 20% and 30% reduction in malaria cases in years 1, 2 and 3, respectively, after achieving high coverage with vector control, if no country level data existed; now many countries have sustained high coverage of vector control interventions and should have country-specific data/historical trends to more accurately estimate any decline in the incidence of acute febrile illness or malaria.
- Seasonal Malaria Chemoprevention: In areas in which SMC is successfully implemented, countries may expect a reduction of at least 50% of the malaria burden in children less than five years of age. Countries should, however, base their estimates on any available country-specific data to adjust their quantifications for children less than five years of age whenever possible.

- *Increased malaria diagnostic coverage:* Malaria diagnostic testing will identify febrile patients who do not have malaria and will not require treatment.
- If universal access to diagnosis has not yet been achieved (or maintained): Countries should adjust their ACT requirements depending on their success in having all suspected cases receive a confirmatory test by applying a factor based on country data to account for those cases treated without confirmation. For example, if 50% of suspected cases receive parasitological testing, countries will need to factor in the ACT needs based on the test positivity rate of the 50% tested (including those that test negative, but where health workers don't comply with the results) as well as ACTs for the 50% of suspected cases that are not tested). The achievements may be different in different sectors (e.g. private vs. public) and geographies, and adjustments should be made accordingly.
- Stock outs: Care should be taken when using consumption as a basis for quantification if stock outs have occurred. Continuing to provide insufficient commodities will only ensure repeated stock-outs.
- Expectations of increased access: Adjustments to ACT requirements may be needed if a country is planning to expand health services (whether through increasing the number of public health facilities, engaging the private sector or community-based efforts). A critical consideration is whether these efforts will increase the number of patients accessing care or just provide additional options of where people can seek care (the former would require an increase in ACTs needed whereas the latter may not).

Other factors to consider in quantification exercises include existing stocks (and expiry dates), needs across age bands, health worker adherence to test results, reporting rates (over and under), and the influences of changes to the organization of the health system (e.g. the introduction or dissolution of pay for service schemes). In addition, *reasonable* buffer stocks based on country context should be included.

An updated comprehensive gap analysis including partner and government contributions should be used for the funding request to help identify needs and gaps as well as prioritize activities (see RBM CRSPC gap analysis guidance and tool). Please ensure that the gap analysis submitted on the Global Fund template is consistent with the other gap analyses conducted in country.

01 Public sector

To date, the focus of the majority of case management resources requested from the Global Fund has been for public sector delivery of facility-based treatment. Facilities should aim for 100% of suspected malaria cases diagnosed, confirmed cases appropriately treated and recorded in line with WHO's T3 initiative. High quality service delivery endures through the following: appropriate training and supervision of health workers; robust quantification and supply chain; demand creation/education of care seekers; quality assurance and pharmacovigilance, and accurate and timely data.

02 Private sector

The private health sector includes a wide range of health care providers, including medical practitioners, licensed and unlicensed pharmacies, unlicensed drug vendors, authorized services belonging to private companies, and not-for-profit services such as non-governmental organizations (NGOs) and faith-based organizations (FBOs). The not-for-profit private sector often plays an important role in providing access to quality services, while the informal private sector may be a major source of irrational treatment, sub-standard medicines and under-reporting (and non-reporting) of malaria cases. While there has been considerable progress in improving both access and quality through public and community-based delivery channels, case management through the private sector requires considerable further attention.

Recognizing the importance of the private sector, the Global Fund has added a technical brief developed by partners outlining key elements and potential strategies to engage the private sector in malaria. In addition, the ACT co-payment mechanism (formerly the Affordable Medicines for Malaria Initiative) is still employed by some of the initial pilot countries and remains an option for continued Global Fund support.

03 Community-level

Many countries provide and/or are in the process of scaling up integrated community case management (iCCM) of febrile illness that usually includes, but is not limited to, diagnosis and treatment of malaria, diarrhea and pneumonia. If successfully implemented, iCCM can contribute significantly to the reduction of childhood morbidity and mortality.

Successfully scaling up iCCM requires early attention and planning to overcome challenges such as supply chains, enhancing supportive supervision, lack of financing for non-malaria commodities and community health worker (CHW) attrition. Many countries have begun addressing these barriers. Examples are the provision of a financial stipend and/or including CHWs as Ministry of Health staff to improve retention, scaling up of malaria services within community case management while awaiting for resources for the other disease components, and implementing innovative solutions to improve supply chain and data collection such as mobile platforms and other m-health interventions.

The Global Fund will fund most components of an iCCM platform (Table 1). Provision of the additional, relatively low cost commodities, such as respiratory timers, oral rehydration salts, zinc and antibiotics, not financed by the Global Fund, is an excellent investment opportunity for governments and other partners to show their commitment to improving child survival outcomes. Applicants should outline the needs and sources of funding for the commodities <u>not</u> provided by the Global Fund. As funding and supply of non-malaria commodities has been a problem in many countries, countries should match scale up plans with the available resources for the full iCCM package. If resources and/or supplies for non-malarial acute febrile illness are not available simultaneously during implementation, the malaria component should continue as planned.

Table 1. Essential components of iCCM and eligibility for Global Fund support

Essential iCCM Components	Global Fund Supported	
Training and salary costs for CHWs	Yes, provided that the CHWs are directly involved in	
	malaria management	
RDTs for malaria diagnosis	Yes	
ACTs for malaria treatment	Yes	
Respiratory timers for pneumonia diagnosis	No*	
Antibiotics for pneumonia treatment and ORS and	No*	
zinc for diarrhea treatment		
Supportive supervision	Yes	
Supply chain system strengthening	Yes**	
Health information system strengthening	Yes**	

^{*}Commodities not funded by the Global Fund provide a co-funding opportunity for governments or other development partners to invest in the iCCM platform.

04 Therapeutic efficacy surveillance

Monitoring the therapeutic efficacy of antimalarial medicines should be a routine activity of malaria programs. Therapeutic efficacy studies should be conducted at least once every two years. These prospective evaluations of patients' clinical and parasitological responses to directly observed treatment for uncomplicated malaria allow for timely detection of resistance to antimalarials and provide evidence to guide national malaria treatment policy.

^{**}Note that in the funding request, these two components should be included in the appropriate RSSH modules, while the remaining components should be included in the malaria case management iCCM module.

05 Quality assurance of pharmaceutical and diagnostic products and service provision

Programs using Global Fund funding to purchase goods and services must comply with the Global Fund's procurement and quality assurance policies. Recipients should also ensure that the procurement of health products apply the principles set forth in the WHO Model Quality Assurance System for Procurement Agencies. Post-procurement quality control and assurance for drugs and diagnostics including post-marketing surveillance should also be considered.

Additionally, quality assurance for service delivery should also be considered (e.g. supportive supervision, health facility surveys). Accurate parasite-based diagnosis is essential, not only to provide the correct diagnosis to the patient, but also to accurately measure malaria burden. Quality assurance programs should accompany parasite-based diagnosis with microscopy or RDTs to ensure that staff are competent, perform well and can employ new tools (e.g. positive control wells).

06 Particular issues related to Plasmodium vivax

Treatment of *Plasmodium vivax* (and *P. ovale*) should follow standard WHO guidelines. The above-mentioned general issues regarding case management also apply to treatment of *P. vivax*.

As the only available drug to treat the liver stage of *P. vivax* (primaquine (PQ)) causes mild to severe (potentially life-threatening) hemolysis in patients who are G6PD deficient, testing for G6PD deficiency in *P. vivax* malaria cases should be considered an integral part of ensuring universal access to diagnosis and treatment. It should be incorporated into national treatment guidelines, and services should be made available as tools are developed (possibly with referral of patients from lower to higher level health facilities for more complex laboratory testing, if required).²

G6PD testing is most commonly conducted by means of the laboratory based fluorescent spot test (FST) and not generally available outside hospitals. The Global Fund has supported FST use and will continued to do so. Recently, rapid screening tests (e.g. CareStart® RDT) that can be used at peripheral health facilities have become commercially available. As both of the aforementioned tests are qualitative and not quantitative, there remains a real, significant risk that some heterozygous females may not be properly diagnosed (as the test will not identify them) and if given PQ, can still hemolyze substantially. Due to remaining quality assurance challenges and until further guidance from WHO is available, the Global Fund will not support the procurement of these G6PD point of care RDTs unless the request is part of a pilot introduction; part of implementation research with an appropriate evaluative framework with the support of WHO (and any other relevant TA provider); or until the test has received WHO prequalification.

If requesting funding for PQ, countries must demonstrate that they have an adequate monitoring system for detecting and managing hemolysis (irrespective of whether a country employs G6PD deficiency testing or not). This includes a pharmacovigilance system including significant patient education and appropriate follow up and referrals.

Where no G6PD test is available, it is difficult to generalize on the correct approach to patient management, because each individual assessment depends on the risk of adverse consequences (related to the likely dose of primaquine required, the prevalence and severity of G6PD deficiency in the area, the degree of anemia and the availability of blood transfusion) and the potential benefits (related to the probability of relapse). In some circumstances, the assessment will favor withholding primaquine, and in others it will favor starting radical treatment after educating the patient about the possible risks, and informing the patient that they should stop the drug if they become ill or their urine becomes red or black.

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 $^{^2}$ Please note that G6PD testing does not need to be conducted with single dose primaquine (0.25 mg of base/kg) for *P. falciparum* as the risk of dangerous heamolysis even in severely deficient individuals is unlikely.

IV. Vector Control

Universal coverage of all people at risk of malaria with long lasting insecticidal nets (LLINs) or indoor residual spraying (IRS) remains the goal for all countries in the malaria control phase. For areas with ongoing local malaria transmission (irrespective of both the pre-intervention and the current level of transmission), WHO does <u>not</u> recommend the scale-back of vector control. For areas where transmission has been interrupted, an analysis of the risk of resurgence is critical. The scale-back of vector control should only be considered based on a detailed analysis that includes: i) assessment of receptivity and vulnerability, ii) active disease surveillance system, and iii) capacity for case management and vector control response. To allow such a comprehensive assessment, investment into health systems, particularly in the strengthening of disease and entomological surveillance, will be a prerequisite. Only once a strong health information system is in place can areas for geographical scale-back be identified; timely detection of resurgences and an appropriate response will also depend on such capacity.

With the spread of insecticide resistance and changes in vector behavior in response to control measures, appropriate and effective vector control has become more challenging. Decisions on which method(s) to choose and where must be based on both disease and entomological factors. Vector control strategies should thus include a clear plan for entomological surveillance, as well as for insecticide resistance management.

07 Long lasting insecticidal nets

If a country employs long lasting insecticidal nets (LLINs) as the tool for universal coverage with vector control (whether national or subnational), countries should apply a combination of mass, free LLIN distributions and continuous free distributions through multiple channels, in particular through antenatal care (ANC) and immunization (EPI) services, and may investigate the potential of delivery through alternate channels (e.g. schools) to maintain universal coverage. Mass campaigns should be repeated at an interval of three years. Continuous distribution channels should be functional before, during, and after the mass distribution campaigns to avoid any gap in universal access to LLINs.

The Global Fund's priority is to ensure universal access with LLINs, or at least the highest possible coverage within a given budget. To maximize coverage, LLINs should be of a standard size with a maximum height of 180cm and be rectangular in shape. The Global Fund generally does not support more costly net sizes or shapes.

New types of LLINs, namely nets treated with pyrethroid insecticide and the synergist PBO, have become available, and WHO is presently evaluating other new products. The Global Fund will support deployment of pyrethroid + PBO treated nets or new generation nets anticipated to arrive on the market in 2017, provided that the plan for their deployment is fully consistent with WHO recommendations and that all aspects of these recommendations can be met by the existing budget or from an alternative funding source. For pyrethroid + PBO treated nets, key criteria set by WHO are that present coverage levels are maintained, that deployment takes place on a pilot exploratory scale only, and that such deployment is accompanied by robust evaluation.

Campaign distribution of long lasting insecticidal nets

Long lasting insecticidal net distribution campaigns should aim to achieve 100% coverage of the entire targeted population at risk of malaria. Countries should develop a clear plan as to how this is to be achieved. When carrying out a universal coverage campaign, nets should be given to households at the rate of 1 net for every 2 household members, rounding up in the case of an uneven number of people (e.g. 2 LLINs for a household of 3 individuals). The procurement ratio must be adjusted to allow for this rounding up; this implies a quantification factor of population/1.8 unless local data are available that indicate that a different ratio is more appropriate to reach the set target. If the population census to estimate the number of LLINs needed is more than 5 years old, population projections may be inaccurate. In these cases, the country can consider including a buffer of up to 10% of the estimated number of required nets or use data and justify from previous distributions.

If distribution channels other than mass campaigns, such as ANC, EPI and schools, are well established in the country, it may be necessary to account for the presence of LLINs distributed through these channels when planning a campaign. Existing nets should be taken into account (by not replacing existing LLINs in good

condition with new LLINs) if the population coverage of LLINs is greater than 40% and the average (mean) age of existing LLINs is less than two years. In such cases, countries have three key options: i) to conduct campaigns designed to close coverage gaps by targeting former LLINs users that no longer have a net; ii) investigate whether further strengthening of continuous distribution channels could be sufficient to maintain coverage over time; or iii) a combination of i) and ii) whereby a stepwise transition away from campaigns is undertaken.

In general, it should be noted that "mop-up" campaigns designed to fill in gaps in coverage in areas that received insufficient nets during a campaign to ensure universal coverage present tremendous challenges in quantification and implementation, and are not recommended. Similarly, "hang-up" campaigns, whereby users are helped individually or in small groups to hang their nets, are not considered value for money. Other community contact points (e.g. including messaging on LLIN use when training community health workers and health facilities workers or reaching out to community leaders) should be considered to ensure that LLIN usage messages are reaching households.

Monitoring and evaluation of LLIN distributions, be it through mass campaigns or other distribution channels, should follow guidance from the Alliance for Malaria Prevention (AMP). Global Fund resources should not be used to meet the needs of partners with specific, but non-essential, data requirements. These partners should communicate their needs to the national program early in the process and pay for collection of these additional data themselves.

Continuous distribution of long lasting insecticidal nets

Whilst universal coverage campaigns achieve high and equitable coverage in a short time, coverage drops if they are not supplemented by continuous distribution. Continuous distribution channels are considered to include ANC, child health and immunization services; schools; community-based networks; occupation channels (e.g. plantations, soldiers, mines, farms) and the private/commercial health sector (including social marketing). It is essential to supplement campaign distribution with a combination of some of these channels (e.g. LLIN delivery through ANC and EPI to pregnant women and infants) to sustain a high level of coverage, particularly among the most vulnerable groups.

Continuous systems for LLIN delivery can be used in two ways. On a relatively small-scale (e.g. using delivery through ANC and EPI only) to provide nets for vulnerable household members before, during and after campaigns, or on a much larger scale (e.g. adding regular distribution through schools or community structures to ANC and EPI) to fully replace mass campaigns. Pilot studies in Tanzania, Madagascar, South Sudan, Ghana and Nigeria indicate that large-scale school or community channels can - with large-scale implementation - deliver enough nets to maintain universal coverage, but large-scale continuous strategies may not be feasible in all contexts. Until a continuous distribution strategy is well established and is functioning at a level to sustain universal coverage over time, countries should plan for mass distribution every three years to maintain full population coverage. Quantification for continuous delivery will depend on which of the above channels are being used in a given context and what their respective reach is (e.g. ANC attendance rate).

Environmental compliance for long lasting insecticidal nets

Distribution of LLINs can generate considerable waste that can be hazardous to both humans and the environment. Countries should include appropriate measures to manage disposal of packaging materials and/or consider 'naked' nets or biodegradable packaging and plan for disposal of contaminated materials (through high temperature incineration or burying, per WHO guidelines). Retrieval of LLINs from households is not encouraged as nets can be repurposed and the waste generated (and resources required) from collection is considerable.

08 Indoor residual spraying

The key issues for IRS are summarized in the WHO Policy Brief accompanying this document and the WHO operational manual for IRS. Note that some new policy recommendations have been introduced in response to evidence that insecticide resistance, especially pyrethroid resistance, is spreading rapidly in most parts Africa. The main questions about IRS: "Where to do it?"; "What insecticide to spray?"; "How often?" and "What other interventions to use in combination?" must be seen through the perspective of insecticide

resistance management. The most basic resistance management strategy is to spray different classes of insecticides with different modes of action in rotation on an annual basis or, more pragmatically, every two years, although rotation can be difficult due to the limited insecticide choices. Spraying the same insecticide repeatedly year after year in the same places is to be avoided, as is the combination of high LLIN coverage with pyrethroid-based IRS. Given the high potential cost, IRS in malaria endemic areas should only be initiated if long term financing is assured. If IRS is proposed for Global Fund financing, a description of long term IRS financing not reliant on Global Fund support should be included in the funding request. While a single spray application is an appropriate response to malaria epidemics if it is conducted early enough in the course of the outbreak, this type of intervention is too short-lived to be considered of value in areas with ongoing high transmission. Therefore, unless it is clear that IRS can be sustained over time, the Global Fund will not support its initiation in new areas.

Environmental compliance for indoor residual spraying

For all spray programs supported by the Global Fund, comprehensive health and environmental compliance safeguards need to be in place. This has proved challenging in several countries where Global Fund supports IRS. Appropriate environmental contamination containment measures, waste management and disposal, as well as personal protective equipment must be included in every IRS program, and it needs to be described how these safety aspects will be monitored.

09 Combining long lasting insecticidal nets and indoor residual spraying

A number of countries have deployed LLINs and IRS in combination in the same geographical area in an attempt to accelerate the reduction of transmission. However, the evidence for enhanced protection against malaria resulting from the combination of IRS and LLINs is currently not clear. Based on WHO guidance, the Global Fund requests its grantees to prioritize delivering either LLINs or IRS at high coverage, and to a high standard, rather than introducing the second intervention as a means of compensating for deficiencies in the implementation of the first. Combining IRS and LLINs can only be considered for managing insecticide resistance, but this only applies once universal coverage with one method of vector control of all at-risk populations is ensured with the available funding (and other high priorities are met such as comprehensive case-management), and must be supported by entomological data (recent insecticide susceptibility data at a minimum). The request will need to be consistent with strategies proposed as part of a national insecticide resistance monitoring and management plan (see below section).

10 Insecticide susceptibility monitoring

Effective malaria vector control is reliant on knowledge of local vector species and their susceptibility to insecticides, as well as on vector and human behaviors that may allow mosquitoes to avoid contact with interventions and thereby maintain residual transmission. Periodic collection of such data is essential to inform vector control strategies and track their impact on malaria transmission. The Global Fund encourages applicants to clearly outline their entomological monitoring needs and how these will be addressed. Within this area, the Global Fund particularly encourages applicants to ensure that routine monitoring of insecticide susceptibility is being planned and budgeted for.

Following an increase in entomological surveillance in malaria-affected regions in recent years, it has been documented that resistance in several important malaria vector species is increasing. To monitor this development, and to provide countries with the evidence required to decide on how to manage insecticide resistance, all countries are requested to conduct insecticide susceptibility testing using WHO guidelines at least once per year. All four insecticide classes approved for public health use (organophosphates, pyrethroids, carbamates, organochlorines) should ideally be included in these tests. Testing of those classes in use or planned for use should be prioritized. Budgets should include funds for follow-up investigation, such as intensity and synergist assays, to allow comprehensive assessments in areas where resistance to pyrethroids and/or other insecticides in malaria vectors is detected.

11 Insecticide resistance management

Effective malaria vector control faces the significant threat of widespread and increasing insecticide resistance. Failure to take steps to mitigate this threat is likely to have severe consequences, both in terms of an increase in the burden of disease and in direct economic costs. The Global Plan for Insecticide Resistance Management (GPIRM) outlined a comprehensive plan for global, regional and national action. To support GPIRM implementation at country level, WHO has developed a framework for development of national insecticide resistance monitoring and management plans. It provides a useful template and specific guidance on how to integrate insecticide resistance monitoring and management activities into national malaria strategic plans. While the framework is undergoing finalization, the latest draft can be requested from WHO. The Global Fund requires all recipients of malaria grants, particularly those in the control phase, to put in place an insecticide resistance monitoring and management plan based on the WHO framework, and to use the development of such plans as an opportunity to identify resource requirements to ensure effective entomological surveillance including regular insecticide susceptibility monitoring.

12 Quality assurance of vector control products

Programs using Global Fund funding to purchase goods and services must comply with the Global Fund's procurement policy. Recipients shall also ensure that the procurement of health products complies with the principles set forth in the WHO Model Quality Assurance System for Procurement Agencies and shall develop and fully maintain at all times a quality assurance system in accordance with those principles. As for all health products, recipients should ensure that vector control products comply with the relevant national legal requirements established in the country. Recipients should develop and maintain a system acceptable to the appropriate national regulatory authority for reporting any defects.

For vector control products the key elements of quality assurance are:

- 1) Sourcing only products with a recommendation for use against malaria vectors from the WHO Pesticide Evaluation Scheme (WHOPES) and compliant with the WHO specifications published by WHOPES.³ With a move of the vector control products review process to the WHO Prequalification Team in 2017, these requirements will be updated to include being listed as a prequalified product as a requirement;
- 2) Supplier/manufacturer should be asked to provide a Certificate of Analysis for each batch of the product being actually supplied;
- 3) Pre-shipment inspection and sampling performed by an independent sampling agent according to WHO4 guidelines and/or International Organization for Standardization (ISO) standards;
- 4) Pre-shipment testing conducted by an independent quality control laboratory (WHO prequalified or ISO 17025 or Good Laboratory Practice (GLP) accredited) to determine that the product conforms to its finished approved WHOPES specifications according to the WHO/CIPAC test methods⁵;
- 5) Testing on receipt in country (post-shipment quality control testing), should only be conducted if specific risk related to transport have been identified or specific concerns on potential product performance justify this additional expense;
- 6) Tender conditions should include provision for free of cost replacement of shipments that fail in QC check and disposal of failed lots;
- 7) Post-marketing surveillance may be required, depending on product and context, to monitor performance over time to ensure that products continue to conform to their specifications and/or recommended performance as set by WHO. For LLINs, this may require both testing of physical durability and insecticidal efficacy. The insecticidal active ingredient content will decline during usage and may be determined only if necessary. For IRS products, bioefficacy on sprayed surfaces of different nature (e.g. mud, brick), as applicable, should be periodically conducted according to WHO procedures when an insecticide is first introduced into a country. Subsequent measurement of insecticide decay on sprayed surfaces may be done only if necessary, as it will incur additional expense.

Post-marketing surveillance of LLINs is best carried out using a prospective study design linked to a mass distribution campaign. Given that it requires considerable resources, the need for post-marketing surveillance

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³ http://who.int/whopes/quality/newspecif/en/

⁴ http://whqlibdoc.who.int/publications/2012/9789241503426 eng.pdf

⁵ http://cipac.org/index.php

needs to be considered in the context of other program priorities, available resources and programmatic context. Countries that have no country-specific data on certain LLIN or IRS products, or where anecdotal data on poor performance of certain products may be available, can make post-marketing surveillance a priority. Agreement on the need and scope of the proposed activities should be reached by in-country stakeholders including the national regulatory authority in charge, and be justified as part of the funding application. All studies should follow WHO guidance. For LLIN durability further practical information is comprehensively captured in the PMI durability toolkit.

13 Entomological capacity building

Progress in global malaria control over the past decade was largely gained through investments in vector control. In order to sustain and build further on these gains, there is a need to improve the efficiency of malaria vector control, including through better selecting and targeting of interventions, and effectively managing anopheline resistance to insecticides. National staff can only meet these challenges with the training, support and career structures required to be able to effectively plan, monitor, evaluate and manage control program efforts. Investment in human resources and the particular systems for public health entomology and vector control, while requiring initial investment, will ultimately save money, ensure the gains of the past decade are not lost, and enable us to accelerate progress in the control and elimination of malaria.

The Global Fund fully supports WHO's recommendations for entomological capacity building and therefore requests ministries of health to ensure that their national malaria control program has the basic human and infrastructure capacity to support vector control and entomological surveillance, including monitoring implementation quality, insecticide resistance and use of entomologic data for decision making. Furthermore, it is suggested that an inter-sectoral coordination mechanism, including representation from agriculture and other relevant bodies and led by the Ministry of Health, is established or strengthened. The purpose of this mechanism is to develop a long-range strategic plan for building human resources and systems for public health entomology and vector control. Financial resources required to support these activities can be requested as part of the funding application.

V. Preventive Therapies for Malaria

14 Intermittent preventive treatment

Intermittent preventive treatment in pregnancy

IPTp is a core intervention for malaria. Scaling up to the WHO recommended number of doses (at least three doses of sulfadoxine-pyrimethamine (SP) after the first trimester) has been challenging. Despite these challenges, IPTp remains an impactful and cost effective intervention. Applicants should evaluate bottlenecks in its delivery and potential solutions to improving uptake, both specific to IPTp itself as well as improving ANC attendance and service delivery. Provision of SP can be included in Global Fund applications but often governments choose this low-cost commodity as part of their counterpart financing commitment. Intermittent screening and treatment of pregnant women is not recommended as it has shown to be less effective than IPTp.

Intermittent preventive treatment in infants

WHO recommends intermittent preventive treatment in infants (IPTi) with SP for infants co-administered with DTP2, DTP3 and measles immunizations through routine EPI in sub Saharan Africa in areas with moderate to high malaria transmission (annual entomological inoculation rates \geq 10) and where parasite resistance to SP is not high (prevalence of Pf dhps 540 mutation of \leq 50%). Global Fund will support implementation of IPTi under these parameters. Programs should monitor the impact on immunization services and performance as well as pharmacovigilance and efficacy of SP. To date, uptake of IPTi has been limited, with only two countries introducing it (Chad and Sierra Leone).

15 Seasonal malaria chemoprevention

SMC is an intervention endorsed by WHO in 2012. SMC consists of providing three to four monthly treatment courses of sulfadoxine-pyrimethamine + amodiaquine (SP+AQ) to children under-five during the malaria

transmission season, in the Sahel sub-region in Africa.⁶ Most SMC-eligible countries have introduced it and have plans to scale up. Applicants should include data indicating the eligibility of the areas chosen for implementation as well as an overview of the implementation plan including pharmacovigilance.

Please note that previous issues of SP+AQ availability have been addressed and there should be sufficient supply going forward.

16 Malaria vaccine (referred to as RTS,S)

In October 2015, WHO jointly convened the Strategic Advisory Group of Experts (SAGE) on Immunization and the Malaria Policy Advisory Committee (MPAC) to review all evidence regarding RTS,S relevant for global policy. SAGE/MPAC recommended that pilot implementation of RTS,S occur in certain areas of 3-5 sub-Saharan African countries, administering 3 doses of the vaccine to children aged 5-9 months of age with a fourth dose 15-18 months later.

Countries outside of any potential pilot will not be able to utilize Global Fund resources for this intervention until the WHO recommendations for wider deployment of the vaccine are complete.

17 Mass drug administration

Mass drug administration (MDA) has been recommended by WHO for some specific situations with the aim of reducing/interrupting transmission, rapidly reducing malaria morbidity and mortality or preventing relapses and resulting malaria transmission. In situations other than those that are realistically approaching elimination, epidemics or complex emergencies, WHO does not recommend MDA.

If MDA is being considered for elimination "acceleration," countries should ensure there is effective and accessible vector control and case management services and strong surveillance for both. In addition, there must be minimal risk of re-introduction If the transmission of malaria is not interrupted or its importation not prevented, and the vectorial capacity is not reduced and maintained at a very low level, transmission eventually returns to its original level once MDA is terminated.

Not all settings will require an accelerated approach, as transmission may already be sufficiently low not to require further dramatic transmission reduction measures and other ongoing interventions may be just as efficient.

MDA approaches can be considered for Global Fund support when they are implemented in combination with high coverage of core vector control interventions, access to malaria diagnosis and treatment and effective surveillance; or for exceptional emergency situations where the primary aim is to prevent morbidity and mortality rather than interrupt transmission (e.g. outbreaks).

Programs should include a description of the epidemiology and rationale for employing MDA, as well as the proposed drug to be used and plans for monitoring efficacy and safety. In addition, programs should monitor susceptibility to the drug used along with that of the first- and second-line treatment regimen(s).

VI. Surveillance

Surveillance, monitoring and evaluation are critical to achieving the objectives of the GTS and AIM and should be prioritized as a core intervention, regardless of the epidemiology of malaria in targeted areas. They are a central element of malaria program planning in which the malaria situation of a country or area is assessed and plans are established to make the most effective use of resources.

While information is critical for program planning, implementation and measuring impact and program performance, it is not the sole preserve of malaria program managers. Information can be used to lobby

⁶ WHO Global Malaria Programme (March 2012). WHO Policy Recommendation: Seasonal Malaria Chemoprevention (SMC) for Plasmodium falciparum malaria control in highly seasonal transmission areas of the Sahel sub-region in Africa.

external stakeholders for the required resources. The performance of malaria programs can also be enhanced if information from program planning and monitoring is made more widely accessible.

Multiple data sources are used in malaria disease surveillance, monitoring and evaluation, including routine information systems, household and health facility surveys, entomological data collection, malaria mapping and longitudinal studies. Their role and relative importance changes as programs proceed along the continuum from high transmission to malaria elimination. Sources should also include the different parts of the health system (public, private, community) and different administrative levels.

In addition to the data sources outlined, programs should consider how malaria information will be analyzed and used to generate data for decision making and if there are appropriate forums and mechanisms in place to assess quality, completeness, representativeness and timeliness. Countries should also be able to articulate the gaps in data reporting, collection, analysis and use and should be encouraged to articulate how they could use external resources to address identified gaps during implementation

Requests for investments to routine health information systems need to explain how the transfer of information will be integrated with other diseases tracked in the system. Requests should also articulate the ability for points of care to generate malaria-specific information on suspected cases receiving parasitological diagnosis and whether confirmed cases receive treatment. Large national household surveys (e.g. MIS, DHS, and MICS) need to be carefully planned to generate the required useful information, and spaced appropriately as to not detract from routine data collection activities.

VII. Social and Behavior Change Communication

When tailored to the specific country context and needs, social and behavior change communication (SBCC) plays an important role in promoting uptake, utilization, adherence and demand creation for malaria interventions and achieving individual-level and public health impact. SBCC can target beneficiaries, health service providers and policy makers. For malaria prevention, SBCC should be used to promote correct and consistent use of LLINs, acceptance of IRS and adherence to spray operator instructions, early and regular ANC attendance, and adherence to national malaria in pregnancy guidelines. For case management, SBCC should be used to promote prompt care seeking, demand for confirmatory testing, compliance with prescribed treatment, and adherence to national case management guidelines.

National malaria SBCC strategies should reflect malaria prevention, control, and elimination objectives outlined in the National Malaria Strategy. National malaria SBCC strategies should outline an iterative process to plan, design, implement, monitor, and evaluate SBCC activities to achieve stated communication and behavioral objectives.

As communities are now more familiar with core malaria activities and data on access, ownership, usage, and knowledge are more widely available, applicants should ensure their SBCC activities address identified barriers to uptake and use of malaria interventions.

As countries progress towards elimination and malaria starts to pose no obvious problem to public health, programs should consider how to ensure both political and community commitment. Messaging and activities should be adapted accordingly to avoid resurgence and achieve elimination.

SBCC proposals should adopt evidence-based, results-oriented, theory-informed, and context-specific approaches, including those that reflect transmission dynamics and the behavioral factors that might shift as malaria cases decline (e.g., lowered risk perception). Proposals should also include an M&E plan with appropriate output and outcome indicators and budget for necessary data collection activities. SBCC proposals for malaria should build on existing SBCC efforts in other health sectors (e.g., maternal and child health, community systems strengthening [CSS]).

VIII. Malaria Elimination

The GTS sets an ambitious target for at least 10 countries with ongoing malaria transmission in 2015 to eliminate malaria by 2020. While not all countries nearing elimination are eligible for Global Fund funding, many are. Understanding the current and historical transmission dynamics to target interventions appropriately is essential and while the combination of malaria interventions may vary by country context, common, core elements for elimination include a strong and sensitive surveillance system and political commitment (including domestic financing).

When considering readiness for elimination, a country should review its stratification considering the lowest geographical level making operational decisions. Tailoring the intervention strategies to the different strata takes careful consideration which should be described, as applicable, in the funding request. In addition, a critical analysis of the strengths and weaknesses of the health system, particularly the surveillance system, the care-seeking behavior, and the roles of the community and private sector, should be undertaken.

Case management should focus on 100% parasite-based, quality assured diagnosis, ensuring universal access to appropriate treatment including gametocytocidal primaquine and follow up for 28 days. G6PD testing does not need to be conducted with single dose primaquine (0.25 mg of base/kg) as the risk of dangerous hemolysis even in severely deficient individuals is unlikely. Note that RDTs should not be used to document clearance, as they can remain positive due to persistent antigenemia. Nucleic acid amplification tests (NAATs) (e.g. polymerase chain reaction or loop mediated isothermal amplification) are tools to diagnose low density malaria infections difficult to identify through RDTs or microscopy. These tools should only be implemented under the following conditions: where transmission is low; where there is already widespread implementation of diagnostic testing and treatment; and where there is a low parasite prevalence (<10%).

Vector control should target remaining foci and areas of on-going transmission. Premature withdrawal of vector control can lead to rebound of transmission and should be considered only after a comprehensive analysis of factors mentioned in this section (and with a robust epidemic response plan). Vector surveillance (including susceptibility) should be maintained.

Mass drug administration is discussed in section 5.4.

Routine surveillance, active case detection and foci investigation are recommended as well as outbreak preparedness, which includes epidemic preparedness and response plans, training, etc. The Global Fund does not recommend prepositioning of emergency supplies in most contexts.

Often remaining transmission is focused in certain high risk populations that do not easily access treatment and prevention, therefore, programs may need to adopt different strategies to improve access to these target populations. Cross-border and regional initiatives/interventions should be considered, as applicable.

WHO is in the process of finalizing an operational manual on malaria elimination, expected to be published in 2017.

IX. Populations Affected by Humanitarian Emergencies

Up to 30% of malaria deaths in Africa occur in the wake of war, local violence or other emergencies, such as natural disasters. The massive population displacement that usually accompanies humanitarian crises is likely to lead to an increase in malaria morbidity and mortality. Resource limitations, inaccessibility, insecurity, inadequate infrastructures and lack of capacity are barriers to carrying out effective malaria control and prevention programs in such settings. Humanitarian emergencies can undermine pre-existing malaria control measures and lead to a collapse of health services. To achieve malaria control objectives, especially in the scale-up and sustained control stages, dedicated and tailored efforts to control malaria in humanitarian emergencies must be made as these situations may devolve quickly and lead to a loss of the benefits achieved.

Countries should consider the potential increased vulnerability amongst populations in crisis including internally displaced persons (IDPs) and refugees, but also the impact on local/host communities. In addition,

standard operating procedures may need to be modified (e.g. changes in LLIN mass distribution methodology to ensure quick and high coverage of refugee populations) and contingency planning considered.

Humanitarian emergencies fall under the Global Fund's policy on challenging operating environments (COEs) approved by the board in April 2016. COEs are defined as countries or regions characterized by governance issues, poor access to health services, and manmade or natural crises. Global Fund financing in COEs is generally provided through country allocations. Country allocations may be reprogrammed to respond to crises, including at the sub-national and regional level. During emergencies, Global Fund country allocations may be complemented by financing via the Emergency Fund. Furthermore, in emergencies with significant cross border displacement, the allocation of a host country may be used to support services for incoming populations. Similarly, the allocation from a country of origin may be used in certain circumstances to provide services in a host country, including when said country lacks the capacity to deliver services but is ineligible for Global Fund financing.

X. Resilient and Sustainable Systems for Health

The new focus on building resilient and sustainable systems for health (RSSH) in the Global Fund Strategy 2017-2022 represents a fundamental paradigm shift in thinking about the delivery of health services. Systems for health, different from health systems, do not stop at a clinical facility but run deep into communities and can reach those who do not always go to health clinics, particularly the most vulnerable and marginalized. The new strategy has outlined the following seven objectives for RSSH investments:

- strengthen community responses and systems;
- support reproductive, maternal, newborn, child and adolescent health and platforms for integrated service delivery;
- strengthen global and in-country procurement and supply chain systems;
- leverage critical investments in human resources for health;
- strengthen data systems for health and countries' capacities for analysis and use;
- strengthen and align to robust national health strategies and national disease-specific strategic plans; and
- strengthen financial management and oversight.

These objectives can be achieved by a wide range of activities, which can be designed either at disease-specific or crosscutting levels. With the disease-specific approach, proposed activities are usually aimed at strengthening certain areas of the health system with specific disease outcomes in mind (e.g., procurement and distribution of rapid diagnostic tests for malaria). The scope of crosscutting activities covers broader health system areas affecting more than one disease outcomes simultaneously (e.g. upgrading antenatal care facilities or revising medical and nursing school curricula). Applicants are encouraged to apply for RSSH support and should strongly consider cross-cutting interventions. Funding requests should clearly articulate how the proposed activities improve the performance of the health system in terms of outcomes related to more than one of the three diseases and should also include a robust gap analysis and needs assessment informing the RSSH funding requests.

The reproductive, maternal, newborn, child and adolescent health (RMNCAH) information note provides additional guidance to that outlined below on and procurement and supply chain management systems but applicants are also encouraged to think about how to make use of human resources for health and data systems that support malaria programming to also contribute to building stronger, more integrated, systems for health.

18 Community systems strengthening

The goal of CSS is to develop the roles of key communities in the design, delivery, monitoring and evaluation of services and activities. Applicants are strongly encouraged to include CSS interventions in their proposals. Such activities seek to expand capacity but must also be accompanied by resources to support extensive and meaningful community engagement, not only in service delivery (such as case management and behavior

⁷ As of January 2016, the following countries are classified as COEs: Afghanistan, Burundi, Central African Republic, Chad, Congo (Democratic Republic), Eritrea, Guinea-Bissau, Haiti, Kenya, Iraq, Mali, Niger, Nigeria, Pakistan, Palestine, Somalia, South Sudan, Sudan, Syrian Arab Republic, and Yemen.

change) where appropriate, but also in monitoring the performance of malaria programs at local and national level, and advocating for improved access and accountability where necessary.

19 Reproductive, Maternal, Newborn, Child and Adolescent Health

There are many known RMNCAH interventions that improve the health of women, children and adolescents affected by HIV, TB and malaria. Beyond such disease-specific programming, however, the Global Fund recognizes that without efforts to improve coordination and create integrated delivery channels, health interventions will remain fragmented and resources will be wasted by duplication. When preparing applications that include RMNCAH activities, applicants should consider the inclusion of support for integrated services, such as ANC and iCCM for example, which represent excellent opportunities to maximize the impact of Global Fund support for the health of women and newborns and children respectively with minimum additional investments.

Antenatal care and malaria in pregnancy

ANC constitutes the main point of contact of pregnant women with the health system. The majority of pregnant women, at least 7 out of 10 in most developing countries, have at least one antenatal contact with a skilled health professional. However, to achieve the full life-saving potential of ANC, at least four visits and a package of proven high impact interventions including IPTp, LLINs, information sharing and case management for malaria in pregnancy (MiP) are required.

Efforts should be made to provide LLINs to women as early in pregnancy as possible and to provide IPTp at every ANC visit, beginning in the 2nd trimester. Not only is IPTp lifesaving and easy to implement, it is also highly cost effective for both prevention of maternal malaria and reduction of neonatal low birth weight and mortality. IPTp as a key intervention for pregnant women, combined with LLIN use and effective case management, should remain a priority across stable malaria transmission countries. Starting as early as possible in the second trimester (e.g., 13 weeks), IPTp is recommended for all pregnant women at each scheduled ANC visit until the time of delivery, provided that the doses are given at least one month apart. SP should not be given during the first trimester of pregnancy; however, the last dose of IPTp can be administered up to the time of delivery without safety concerns.

It is vital to expand and strengthen ANC service delivery to ensure that pregnant women have sufficient access to malaria protection and/or treatment. ANC is a key opportunity to not only further malaria control objectives, but also to integrate MiP activities with other synergistic interventions (e.g., prevention and treatment of anaemia in pregnancy, nutrition counselling, etc.). Investing in addressing some of the main ANC challenges, such as late initial contact, low quality of care, and inadequate commodities to administer full requirements of IPTp and LLINs, could increase coverage, address the devastating consequences of malaria in pregnancy, and improve maternal and newborn outcomes overall.

20 Procurement and supply chain management

Malaria health products include: (i) pharmaceutical products; (ii) durable and non-durable in-vitro diagnostic products, microscopes and imaging equipment; (iii) LLINs; and (iv) consumable/single use health products (including, insecticides, general laboratory items and injection syringes) – all of which can be financed out of the grant funds.

Procurement and supply management refers to all activities required to ensure the continuous and reliable availability of sufficient quantities of quality-assured, effective health products to end-users, procured at the lowest possible prices in accordance with applicable laws (Global Fund, 2012). Presenting clear approaches to health products management (including management of potential risks) in the funding request and grant development is critical to the success of grant implementation.

The coordination of all procurement and supply (PSM)-related activities is critical to ensuring timely delivery of quality health products to avoid treatment disruption, stock outs, or delays in distribution campaign of nets. A PSM coordination mechanism, such as a working group or task force, is strongly recommended. Applicants should demonstrate that the systems and the people to manage PSM activities, in compliance with the Global Fund policies and requirements, are in place. If these are not in place, a clear plan for building the required

systems and capacity needs to be presented. Of note, under the framework of a national strategic plan, applicants are encouraged to design interventions that are crosscutting to ensure that a sustainable supply chain system is strengthened, and, as a result helping other national health programs. In this regard, integration plays a vital part. Many funding requests include PSM strengthening, though often in silos for disease components. Crosscutting investments in the health system can be used to facilitate integration as an approach to strengthening procurement and supply chain systems.

Applicants should develop a mapping of PSM arrangements highlighting responsibilities of each stakeholder involved in the health products management including quantification, procurement, storage & distribution systems, information systems. In addition to the commodity costs, budgets should also cover associated management costs such as freight and insurance, customs clearance, storage, distribution, quality assurance including quality control, PSM monitoring and reporting, technical assistance, and capacity building activities costs - according to identified needs.

XI. Community, Rights and Gender

In its strategy for 2017-2022, the Global Fund made a commitment to "introduce and scale up programs that remove human rights barriers to accessing HIV, TB and malaria services" and "to invest to reduce health inequalities including gender-and age-related disparities". Human rights and gender-related barriers include all stigmatizing, discriminatory and punitive laws, policies, practices and harmful gender norms and attitudes that impede people's access to health services. This commitment signals an intensified effort to include and scale up programs to remove human rights and gender-based barriers in national responses to the three diseases, including malaria.

To achieve the goal of universal coverage of malaria program interventions, barriers to accessing all levels of services should be carefully identified and addressed.

To do so, applicants are strongly recommended to take the following steps through an inclusive and participatory country dialogue to:

- 1. Identify those populations who may not be reached by services (e.g. migrants, IDPs, refugees);
- 2. Identify barriers to accessing services and examine how the services are delivered in order to understand what approaches are needed to remove human rights and gender-related barriers;
- 3. Design all programs using a human rights-based approach;9 and,
- 4. Request funding for programs to remove human rights and gender-related barriers to malaria services, under each malaria intervention module if applicable.

Note that during the last cycle of funding requests, countries often did identify particular groups with barriers to services, but many did not outline how they would adapt programming to meet their needs. Additional information on programs to remove human rights and gender-related barriers in the context of malaria can be found in the Human Rights, Gender, and Malaria Technical Brief.

15 December 2016 Geneva, Switzerland

⁸ The Global Fund Strategy 2017-2022: Investing to End Epidemics. GF/B35/02 – Revision 1.

⁹ For a summary of a human rights-based approach to health, please see WHO and OHCHR, 2008: *A Human Rights-Based Approach to Health*, available online.

XII. Key References

Global Fund Information Notes and Technical Briefs

- <u>Building Resilient and Sustainable Systems for Health through Global Fund Investments Information Note</u>
- The Global Fund Human Rights, Gender and Malaria Technical Brief
- > The Global Fund Reproductive, Maternal, Newborn, Child and Adolescent Health Technical Brief

Further selected Global Fund documents

- ▶ Global Fund Strategy 2017-2022 "Investing to End Epidemics." (2016)
- > Applying for funding
- > The Applicant's Handbook. A practical guide to preparing a funding request (2016)
- Funding Request Instructions (2016)
- Global Fund Modular Framework Handbook
- Frequently Asked Questions. The 2017-2019 Funding Cycle (2016)
- > The Global Fund Sustainability, Transition and Co-financing Guidance Note
- ➤ The Challenging Operating Environments Policy

Guidelines and key documents by area from the Global Fund and Partners

Background information

- ► Global Fund concept note development WHO policy brief 2016
- ► WHO | Global Technical Strategy for Malaria 2016–2030

Case management

- WHO | Good practices for selecting and procuring rapid diagnostic tests for malaria
- ➤ RBM CRSPC Gap Analysis Tool
- ➤ The Global Fund Technical Brief: Malaria Case Management in the Private Sector
- The Global Fund Core AMFm Information Note
- ➤ <u>WHO/UNICEF Joint Statement: Integrated Community Case Management (iCCM)</u>
- > WHO | Guidelines for the treatment of malaria. Third edition
- > WHO | Management of severe malaria A practical handbook. Third edition

Therapeutic efficacy surveillance

> WHO | Methods for surveillance of antimalarial drug efficacy

Quality assurance of pharmaceutical and diagnostic products and service provision

- Policies & Principles The Global Fund to Fight AIDS, Tuberculosis and Malaria
- ► WHO | Malaria microscopy quality assurance manual Ver. 2

Particular issues related to P. vivax

➤ WHO | Safety of 8-aminoquinoline antimalarial medicines

Vector control

➤ WHO Information note on the risks associated with the scale back of vector control in areas where transmission has been reduced

Long lasting insecticidal nets

➤ WHO | Recommendations for achieving universal coverage with long-lasting insecticidal nets in malaria control

- ➤ WHO | Conditions for use of long-lasting insecticidal nets treated with a pyrethroid and piperonyl butoxide
- AMP: A toolkit for mass distribution campaigns to increase coverage and use of long-lasting insecticide-treated nets
- Malaria Behavior Change Communication (BCC) Indicator Reference Guide
- ➤ AMP Statement on M&E Best Practices for Partners Supporting National Long-Lasting ITN Mass Distribution Campaigns
- Continuous Distribution Toolkit
- WHO | Recommendations on the sound management of packaging for long-lasting insecticidal nets
- > WHO | Recommendations on the sound management of old long-lasting insecticidal nets
- ➤ WHO | Indoor residual spraying: An operational manual for IRS for malaria transmission, control and elimination.

Combining LLINs and IRS

➤ WHO | Larval source management – a supplementary measure for malaria vector control. An operational manual.

Insecticide susceptibility monitoring / resistance

- > WHO | Test procedures for insecticide resistance monitoring in malaria vector mosquitoes
- > WHO | Global plan for insecticide resistance management in malaria vectors

Quality assurance of vector control products

- Guide to Global Fund policies on procurement and supply management
- > WHO | WHOPES recommended products for malaria vector control
- WHO | Guidelines for monitoring the durability of long-lasting insecticidal mosquito nets under operational conditions
- > PMI | Durability Monitoring Toolkit

Entomological capacity building

> WHO Guidance Note on Capacity Building in Malaria Entomology and Vector Control

Intermittent Preventive Treatment

- > WHO | Intermittent preventive treatment in pregnancy
- ➤ WHO | Recommendations on intermittent screening and treatment in pregnancy and the safety of ACTs in the first trimester
- > WHO | Intermittent preventive treatment in infants

Seasonal malaria chemoprevention

- > WHO | Seasonal malaria chemoprevention
- > WHO | SMC Implementation Field Guide

Malaria vaccine

➤ WHO | Questions and answers on RTS,S/ASO1 malaria vaccine

Mass drug administration

➤ WHO | Recommendations on the role of mass drug administration, mass screening and treatment, focal screening and treatment for malaria

Surveillance

- > WHO | Disease surveillance for malaria control: operational manual
- ▶ WHO | Disease surveillance for malaria elimination: operational manual

Social and behavior change communication

> RBM BCC Strategic Framework

Malaria elimination

- ➤ WHO | Information note on the risks associated with the scale back of vector control in areas where transmission has been reduced
- ➤ WHO | Updated WHO policy recommendation: Single dose primaquine as a gametocytocide in Plasmodium falciparum malaria
- > WHO | WHO policy recommendation on malaria diagnostics in low transmission settings
- ➤ WHO | Recommendations on the role of mass drug administration, mass screening and treatment, and focal screening and treatment for malaria

Humanitarian Emergencies

- Malaria control in humanitarian emergencies An inter-agency field handbook
- ► Alliance for Malaria Prevention | COE Guidelines

XIII. List of Abbreviations

ACT - Artemisinin-Based Combination Therapy

AMP - Alliance for Malaria Prevention

ANC - Antenatal Care

BCC - Behavior Change Communication
CBO - Community-Based Organization
CCM - Country Coordinating Mechanism
CHW - Community Health Worker

COE - Challenging Operating Environment

CRSPC - Country Regional Support Partners Committee (formerly RBM

HWG)

CSO - Civil Society Organization

CSS - Community Systems Strengthening

FBO - Faith-Based Organization

G6PD - Glucose-6-phosphotase-dehydrogenase

GLP - Good Laboratory Practice

GPARC - Global Plan for Artemisinin Resistance Containment
GPIRM - Global Plan for Insecticide Resistance Management

GTS - Global Technical Strategy (for Malaria)

HSS - Health Systems Strengthening

HWG - Harmonization Working Group (of Roll Back Malaria)

iCCM - Integrated Community Case Management

IDP - Internally Displaced Person

IPTi - Intermittent Preventive Treatment in Infants
 IPTp - Intermittent Preventive Treatment in Pregnancy

IRS - Indoor Residual Spraying

ISO - International Organization for Standardization

ITN - Insecticide-Treated Net (used interchangeably with LLIN)
LLIN - Long-Lasting Insecticidal Net (used interchangeably with ITN)

M&E - Monitoring and Evaluation
MDA - Mass Drug Administration
MiP - Malaria in Pregnancy

MNCH - Maternal, Newborn and Child Health MPAC - Malaria Policy Advisory Committee

MPR - Malaria Program Review

NGO - Non-Governmental Organization

OCHA - Office for the Coordination of Humanitarian Affairs

PQ - Primaguine

PR - Principal Recipient

PPM - Pooled Procurement Mechanism (of the Global Fund)

PSM - Procurement and Supply Management

RBM - Roll Back Malaria RDT - Rapid Diagnostic Test

RMNCAH - Reproductive, Maternal, Newborn, Child and Adolescent Health

RSSH - Resilient and Sustainable Systems for Health SBCC - Social and Behavior Change Communication

SMC - Seasonal Malaria Chemoprevention

SP - Sulfadoxine-pyrimethamine

SAGE - Strategic Advisory Group of Experts

TRP - Technical Review Panel WHO - World Health Organization

WHOPES - WHO Pesticide Evaluation Scheme