Documentation related to Sessions 5 and 6 of the meeting
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Malaria Policy Advisory Committee (MPAC) Meeting, 2–4 October 2019

Documentation related to Sessions 5 and 6

Thursday, 3 October 2019			
	Session 5	**Open**	
09:00 – 10:00	Update on the informal consultation to reconsider the formulation of malaria policy guidance Background | Presentation	Dr Rick Steketee	**For decision**
10:00 – 10:45	Technical consultation to review the role of drugs in malaria prevention for people living in endemic settings	Dr David Schellenberg	**For guidance**
10:45 – 11:15	*Coffee break*		
	Session 6	**Open**	**For guidance**
11:15 – 12:00	Update on the technical consultation on malaria case management in the private sector in high-burden countries Background | Presentation	Dr Andrea Bosman	
12:00 – 12:45	Update on the technical consultation on institutionalizing integrated community case management Background | Presentation	Dr Salim Sadruddin	

Malaria Policy Advisory Committee Meeting
2–4 October 2019, Geneva, Switzerland
Background document for Session 5

Informal consultation to reconsider the formulation of malaria policy guidance

Concept note – 17-18 September 2019

Background

WHO uses evidence-informed processes to develop guidance on control malaria. The most robust evidence comes from randomized controlled trials (RCTs), although information from a range of study designs may feed into the policy-making process. By their nature, RCTs generate evidence under tightly controlled conditions. This has led to a tendency for some WHO malaria policies to be overly prescriptive. For example, seasonal malaria chemoprevention (SMC) is recommended where 60% of malaria cases occur in four consecutive months. However, a large proportion of the remaining cases may occur in an additional month or two, raising the question of whether extending SMC for an additional period may be appropriate. Other countries may have slightly less than 60% of their malaria cases in four months – is it appropriate that SMC not be implemented in such settings? Similarly, the specified target group for SMC (children aged XX-5 years) precludes implementation where a substantial portion of disease may occur in older children. Although there is variation in the way that the WHO Global Malaria Programme formulates policy across the different types of interventions (e.g. long-lasting insecticide treated nets [LLIN], treatment, SMC, intermittent preventive treatment in pregnancy) the current formulation of guidance effectively boxes malaria control programmes in, not least because the Global Fund to Fight AIDS, Tuberculosis and Malaria is only able to fund activities compliant with WHO policy. The net result is that malaria control efforts may be overly constrained by the way that policy guidance is currently formulate.

As malaria control improves, underlying heterogeneity in malaria risk is revealed. To further improve control, and to maximize the impact of the limited available resources, a shift in mindset is needed away from a one-size-fits-all to a problem-solving approach. This should involve the deployment of the most appropriate packages of interventions for the range of settings within a country, and this implies the need for guidance which allows flexibility in the implementation of existing tools and strategies.

This informal consultation will explore the advisability of moving from an approach which articulates specific guidance based on the conditions in which specific studies were conducted, to one in which the generalizability of findings from studies informs the casting of policy recommendations. Outcomes measured close to the point of biological activity of an intervention are likely to be more generalizable than downstream, public health outcomes. For example, the ability of an antimalarial drug to prevent infection with sensitive parasites is likely to be the same in all settings. However, the public health impact – and value for money – of a programme which aims to deliver these drugs at specific times to a defined target population is likely to vary widely according to a large range of contextual factors (age pattern of disease, itself a function of malaria transmission intensity, efficiency of delivery system, etc.).

A parallel may be drawn with the evolution of medical practice in Europe over the last 30 years. Previously, patients would be examined, diagnosed and treated by a doctor with little opportunity for the patient, a passive recipient, to engage in the process. Nowadays the patient is expected to ask

WHO/CDS/GMP/MPAC/2019.16

questions, challenge diagnoses and select their preferred course of treatment. The same evolution should apply to WHO's interaction with national malaria control programmes (NMCPs), recognizing that they increasingly need to rationalize malaria control across a range of settings in their countries.

Specific objectives

1. To explore how policy recommendations emerging from WHO guideline development processes can be reformulated to increase generalizability, where appropriate, and support problem-solving approaches in malaria control;
2. Through consideration of specific examples, explore the need for – and feasibility of – reformulating malaria policy recommendations;
3. Articulate principles to guide the formulation of malaria guidance.

Methods

End user participants will be asked to identify examples of policy guidance, with which they have difficulty, before the meeting. Examples of WHO policies from other departments will inform discussion on the breadth of malaria policy recommendations. The evidence needed for different types of policies, and considerations of generalisation from research study results, will be discussed.

Participants

Three main constituencies:

(i) academics and researchers who contribute to the development of evidence;

(ii) WHO advisers responsible for advising the WHO Global Malaria Programme on policy development;

(iii) end users of GMP guidance from NMCPs, the Global Fund and the President's Malaria Initiative (PMI).

Proposed time of workshop

Two working days.

Informal consultation to reconsider formulation of malaria policy guidance

Report on a meeting, 17–18 September 2019, Geneva, Switzerland

This document was prepared as a background document for members of the Malaria Policy Advisory Committee and is not an official document of the World Health Organization.
WHO/CDS/GMP/MPAC/2019.19

Contents

Acronyms

AQ	amodiaquine
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Global Malaria Programme
IPT	intermittent preventive treatment
IPTi	intermittent preventive treatment of infants
IPTp	intermittent preventive treatment during pregnancy
IRS	indoor residual spraying
ITN	insecticide-treated net
LLIN	long-lasting insecticidal net
MDA	mass drug administration
NMCP	national malaria control programme
PICO	population, intervention, comparator group and outcome of interest
PMI	President's Malaria Initiative
SMC	seasonal malaria chemoprevention
SP	sulfadoxine–pyrimethamin
TDR	Special Programme for Research and Training in Tropical Diseases

Glossary

Guideline: A WHO guideline is any document prepared by WHO that contains recommendations and good practice statements for clinical practice or public health policy. The Guidelines Review Committee was established by the WHO Director-General in 2007 to ensure that WHO guidelines are of a high methodological quality and are prepared in a transparent, evidence-based decision-making process.

Recommendation: A recommendation informs users of a guideline about what can or should be done in specific situations to achieve the best possible individual or collective health outcomes. It offers a choice of interventions or measures that are anticipated to have a positive impact on health and implications for the use of resources.

Good practice statement: Good practice statements may be provided in lieu of evidence-based recommendations when there is a high level of certainty that the benefits of the recommended intervention outweigh the harm. Such certainty may be based on a large body of linked or indirect evidence or physical or biochemical properties, or the statement may be based on ethical principles or human rights conventions. Given the high level of certainty, a systematic review and a detailed assessment of the evidence are not required to make the statement.

Operational manual: An operational manual provides detailed practical guidance on implementing a policy recommendation. They may include handbooks, field guides, information notes, reference manuals, frameworks and policy briefs.

Summary

The WHO Global Malaria Programme (GMP) convened an informal consultation to reconsider formulation of guidance on malaria policy in Geneva, Switzerland, on 17–18 September 2019. The meeting was held in response to growing realization that some WHO recommendations on malaria might be overly prescriptive, restricting the use of potentially valuable interventions, while others are unnecessarily broad, with implications for resource allocation. The lack of flexibility of such formulations compromises the ability of malaria control programmes and their implementing partners to solve problems by using mixes of interventions that are suitable to the local context and that limit the impact on resources.

Representatives from the following groups participated in the discussion: users of GMP guidance, including representatives of several national malaria control programmes (NMCPs), the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the United States President's Malaria Initiative (PMI), academics and researchers who generate evidence and WHO advisers to GMP on guideline development.

The objectives of the meeting were:

- to explore how policy recommendations emerging from WHO guideline development can be reformulated to increase their generalizability, where appropriate, and support problem-solving in malaria control;
- by considering examples, explore the need for and feasibility of reformulating malaria policy recommendations; and
- formulate principles for guidance on malaria control.

The participants were aware that WHO has a well-established process for developing guidelines, which is described in a WHO handbook *(1)*. The group stressed the importance of guidance for countries and urged that adequate consideration be given in developing guidelines to the broad variety of contexts in which they may be relevant. Therefore, the transferability of recommendations to settings beyond those in which the evidence was generated should be assessed. Countries require support in deciding on and prioritizing mixes of interventions. A major theme of the discussions was the importance of maximizing the impact of available resources. The group agreed that this is often best achieved by the most effective and cost–effective combination of interventions in subnational contexts, rather than sequential implementation of individual interventions throughout a country. Countries are already stratifying and beginning to tailor interventions to the subnational level, but this is to some extent frustrated by the constraints of existing WHO guidance, which in turn may affect the decisions of international donors.

Key discussion points

- *Reformulating recommendations*

Partners and country representatives gave examples of how current policy guidance could be improved to facilitate national policy-making and priority-setting and funding by international donors. Country representatives provided concrete examples of current policy wording that might be unnecessarily restrictive and described difficulties in deciding on an intervention in a setting that differs, even slightly, from that indicated in the guidance. Participants acknowledged that full advantage is not taken of some existing flexibility, for example in WHO operational guidance and in use of GFATM resources.

- *Updating GMP guidance*

The meeting considered suggestions of topics for which GMP guidance could usefully be reviewed and updated. Situations in which there are insufficient data or experience to make decisions on the suggested changes should be flagged to stimulate the generation of relevant data. A continuous, systematic process should be defined to ensure that priority recommendations are identified and updated rapidly. Prioritization of recommendations for review should be based on country needs.

- *Transferability and learning from implementation*

Participants discussed how evidence is used to inform policy recommendations. Data from randomized controlled trials are considered the "gold standard" basis of policy recommendations. The current recommendations were often made on the basis of the results of such trials, which provide high-quality evidence but in strictly defined settings, so that the wording of the guidance often mirrors the specific setting in which the evidence was generated.

In discussing the generalizability of recommendations, the group explored the procedures used in other technical areas (e.g. HIV). The preferred term "transferability" of evidence refers to extension of a recommendation from the setting in which the evidence was generated, with or without adjustment, to another setting for which there is no evidence; the term "generalizability" is then used in specific cases in which evidence can be applied elsewhere without adjustment. The group thus spoke of the "transferability" of recommendations, which allows interventions to be recommended for use in settings that differ to some degree from those in which the evidence was generated.

The WHO policy development process allows use of various types of evidence. The group discussed the use of non-randomized study designs in evaluating the impact of an intervention that has been adapted for use in different circumstances, resulting in stronger policy recommendations. Theories of change, which outline the steps in which an intervention is expected to have a public health impact, can usefully inform monitoring of contextual parameters. These, in turn, facilitate the development of recommendations and guide their applicability beyond settings for which data exist.

While recognizing the potential benefits of transferable recommendations, the participants noted that transferability should be considered particularly carefully when there are safety concerns.

- *Stratification and mixes of interventions*

NMCP managers described the use of mixes of interventions and reported that their strategic plans increasingly involve stratification of subnational areas and populations, so that different mixes of interventions are used in different settings. The extent to which this is done is sometimes constrained by interpretation of WHO guidance, funders' practices and community and political perspectives. The group recognized the critical role of local data in stratification and prioritization of intervention mixes. Current WHO policies address mainly single interventions and only rarely decisions about mixes of interventions or the trade-offs among interventions within and between epidemiological strata. Malaria control programmes require guidance to define mixes of interventions for solving problems.

Implementation of reformulated guidance should be evaluated and the evidence considered by WHO to continue to increase the strength and transferability of recommendations.

- *A sense of urgency and a window of opportunity*

As many NMCPs will prepare concept notes for the GFATM in the first part of 2020, support in prioritization, for stratification (e.g. according to malaria risk, availability of health facilities and other contextual factors) and for the selection of intervention mixes should be accelerated. A particularly urgent requirement is better understanding of the principles and practices of priority-setting among

NMCPs, donors and other stakeholders. The group therefore prepared a statement for consideration by the Malaria Policy Advisory Committee at its next meeting (see below).

- *Dissemination and operational use of guidance*

Participants reiterated that dissemination could be reinforced and targeted to ensure that users of guidance in countries are well informed. Participants from endemic countries emphasized the importance of support for operational use of guidance and requested assistance in stratification of geographical areas, the best use of different intervention mixes and adaptation of WHO guidance to their contexts. The compendium of malaria guidance was considered a useful re-packaging and overview of the available guidance as it combines "what to do" recommendations with "how-to-do-it" documents – all of which should be considered part of countries' problem-solving approach *(2)*.

Statement from the group *(3)*

The past 15 years have seen a substantial decline in malaria cases and deaths, thanks to the scaling-up of essential interventions, driven by increased investment and reduced commodity costs. However, according to the WMR 2018, progress is slowing, and funding is no longer increasing. Commodity costs could also increase; next-generation nets, which may be more expensive, are needed to address the threat of insecticide resistance. Achieving the GTS targets for reduced morbidity and mortality will require not only additional resources, but also renewed efforts to maximize the impact of the available resources.

With the support of the *High Burden, High Impact* approach, coordinated by WHO and the RBM Partnership to end Malaria, countries are working to develop detailed national strategic plans (NSPs), with robust stratification and tailored subnational intervention mixes, adapted to the local context, in order to achieve national targets.

The goal remains universal coverage of at-risk populations with an appropriate mix of interventions. There is broad recognition that in many cases, the resources available are not sufficient to fund all the elements of these NSPs. In this situation, countries must make difficult choices, trying to make the best use of the limited available resources. The process of stratification, and defining appropriate intervention mixes for each stratum, requires additional data and therefore increased investments in the collection of routine data and surveillance systems.

The informal consultation group is recommending to the Malaria Policy Advisory Committee (MPAC) that:

- *Intervention prioritization should **not** be driven solely by sequentially optimizing single interventions for maximal coverage;*
- *Instead, intervention prioritization should be based on local evidence and aligned to the specific needs of different epidemiological strata/settings as defined in the country's NSP.*

This new data-driven approach moves away from a one-size-fits all perspective. For example, an NMCP might prefer to increase the number of districts covered with seasonal malaria chemoprevention (SMC) rather than distributing long-lasting insecticidal nets (LLINs) in urban settings or other permanently-low transmission settings with stable low-prevalence conditions. Similarly, an NMCP might prefer to cover a larger number of districts with a more comprehensive intervention package, rather than covering very few districts with indoor residual spraying (IRS). It will be critical that countries monitor the impact of these stratified approaches with enhanced surveillance, both to learn from the process, and to identify and rapidly mitigate potential problems. In addition, during implementation, there may be additional opportunities for operational efficiencies, such as targeted supportive supervision for case management.

Of note, the informal consultation group appreciates the concept of "universal coverage", and in striving to save lives, reduce disease and ultimately eradicate malaria, we encourage seeking universal coverage of the right packages of interventions, recognizing that the appropriate mix will vary by setting.

The group encourages the Malaria Policy Advisory Committee to request the WHO GMP secretariat to support countries with the prioritization exercise and for country programs and funders to embrace the flexibilities and additional data required in order to optimize the allocation of limited resources for maximum impact.

Introduction

The WHO GMP convened an informal consultation to reconsider the formulation of malaria policy guidance, in Geneva, Switzerland, on 17–18 September 2019. During the consultation, participants explored the advisability of moving from an approach of providing specific guidance under the conditions in which studies were conducted to one in which the findings of studies are generalized to cast policy recommendations for other settings. The specific objectives of the meeting were:

- to explore how policy recommendations emerging from WHO guideline development can be reformulated to increase their generalizability, where appropriate, and support problem-solving in malaria control;
- by considering examples, explore the need for and feasibility of reformulating malaria policy recommendations; and
- formulate principles for guidance on malaria control.

Three main constituencies were brought together to discuss the issues: users of GMP guidance from NMCPs, GFATM and PMI; academics and researchers who contribute to providing evidence; and WHO advisers responsible for advising GMP on policy development. Annex 1 provides the agenda of the meeting and Annex 2 the list of participants. The meeting was chaired by Dr Richard Steketee.

The Director of GMP, Dr Pedro Alonso, explained the context of the meeting, which included both revision of GMP's policy-making process and the WHO transformation. The aim of GMP is to deliver timely, high-quality guidance to malaria-endemic countries through transparent, consistent, efficient, predictable processes. In May 2018, GMP launched an extensive review of the development and dissemination of guidance on malaria policy by collecting the views of a broad range of stakeholders to better understand their needs and the perceived bottlenecks in policy-making. GMP is now making a series of changes to its processes. In parallel, WHO is undergoing a transformation, which has seen the creation of a new Science Division, which includes the Special Programme for Research and Training in Tropical Diseases (TDR) and a number of new departments, including Research and Knowledge and Quality, Norms and Standards. GMP is working with these two new departments in implementing changes, ensuring close collaboration and direct lines of work across departments. Dr Alonso emphasized that recommendations should be tools for Member States to use in solving problems in their fight against malaria, providing countries with evidence-based advice for decision-making, and WHO guidelines must evolve in response to new evidence and country needs.

Dr David Schellenberg, scientific advisor, described WHO's use of evidence in preparing guidance on malaria control. The guidelines development handbook describes each step in the process *(1)*. A key component is posing questions that address the population, intervention, comparator group and outcome of interest (PICO). The way in which such questions are formulated guides the assimilation of evidence through systematic reviews and informs the final recommendations. The most robust evidence is that from randomized controlled trials, although information from other study designs can be used in policy-making. By their design, randomized controlled trials provide evidence under tightly controlled conditions, which has led to a tendency for some WHO malaria policies to be overly prescriptive. Although the GMP formulates policy differently for different types of intervention (e.g. LLINs, treatment, SMC, intermittent preventive treatment in pregnancy [IPTp]), current formulations of guidance effectively constrain NMCPs, not least because the GFATM can only fund products that comply with WHO prequalification or are approved by a stringent regulatory authority, and it relies on WHO's policy recommendations to guide country plans. The result is that malaria control may be overly constrained by the way in which policy guidance is currently formulated.

Dr John Reeder, Director of Research and Knowledge and of TDR, expressed enthusiasm for the meeting, emphasizing that research should be better coordinated. He described the four main areas of activity of the new department: (1) foresight (looking upstream to product and strategy development) to ensure, for example, that target product profiles are available for all diseases (currently, none of the 187 profiles in the WHO repository are for neglected tropical diseases); (2) setting priorities for research to reach the "triple billion" goals; (3) establishing a better community of practice on research, including strengthened capacity for national ethics reviews; and (4) a better policy for access, to support the translation of research into impact.

1. Perspectives on current policies of the Global Malaria programme

1.1 PATH

Dr Larry Slutsker, Director, Malaria and Neglected Tropical Diseases Center for Malaria Control and Elimination, PATH, provided his institution's perspectives on WHO guidance. Currently, two GMP guideline documents have been approved by the Guideline Review Committee, which include 17 recommendations on vector control, 3 on chemoprevention and about 30 on case management (diagnosis and treatment). In addition, GMP has issued handbooks, manuals, information notes and policy briefs. The Compendium of WHO malaria guidance summarizes the guidelines and related documents *(2)*. Dr Slutsker drew participants' attention to the definitions of a WHO guideline and a good practice statement (see Glossary, above) and noted that good practice statements are used by WHO in situations in which it is not possible to make an evidence-based recommendation and there is a high level of certainty that the benefits of the recommended intervention outweigh the harm.

Dr Slutsker provided examples of GMP policy that is constraining, narrow, technically complex and/or vague. Universal coverage with an effective vector control core intervention (insecticide-treated nets [ITNs] or IRS) is recommended for all populations at risk of malaria in most epidemiological and ecological settings. In settings in which programmes are committed to achieving universal coverage even in areas of low malaria risk, however, this recommendation has an impact on budgets, using funds that are then not available for other interventions. More targeted approaches may be appropriate in certain situations, such as for vulnerable groups in lower-risk areas. In reality, countries are already setting priorities, in the absence of an agreed framework, running the risk of deprioritizing proven interventions in areas or groups at continued risk of malaria. Conversely, the guidance for SMC is constraining. SMC is recommended in areas of highly seasonal malaria transmission throughout the Sahel sub-region.[1] Some formulations of the current GMP guidance recommend a complete treatment course of sulfadoxine–pyrimethamine (SP) plus amodiaquine (AQ) for children aged 3–59 months, at monthly intervals, beginning at the start of the transmission season, up to a maximum of four doses during the transmission season (provided both drugs retain sufficient antimalarial efficacy), in areas in which at least 60% of the total annual clinical malaria cases occur during a short period of about 4 months and where the incidence of clinical malaria is at least 10 cases per 100 children during the transmission season. The policy is thus constrained by the criteria of age, geographical area and disease burden. Consideration could be given to extending the age range (which some countries have already done) and to broadening the criteria for seasonality. It is important to recognize that data on the safety of SP + AQ in older children are relatively limited.

[1] This version of the SMC recommendation is available as a WHO policy recommendation *(4)* and is widely recognized. The current reference recommendation, in the third edition of the *WHO Guidelines for the treatment of malaria (5)*, is less constraining.

Another restrictive recommendation is that for SP in intermittent preventive treatment in infants (IPTi). This intervention is recommended at the time of vaccination of infants with the second and third doses of diphtheria–pertussis–tetanus or pentavalent vaccine and of measles vaccine in routine immunization programmes in countries in sub-Saharan Africa; however, it is a technically complex recommendation, as it requires demonstration that the frequency of a molecular marker of resistance to SP (the *DHPS 540* mutation) is present < 50%. As a result, data are frequently not available to inform policy decisions, and there has been very little uptake of the strategy.

The policy for larviciding illustrates another potential problem. The recommendation calls for regular application of biological or chemical insecticides to water bodies (larviciding) as a supplementary intervention in areas where high coverage with a core intervention has been achieved, where the aquatic habitats of the principal malaria vector(s) are few, fixed and findable, and where its application is both feasible and cost-effective. As the term "few, fixed and findable" is difficult to interpret, the recommendation is vague. A number of countries are investing considerable resources in larviciding programmes which are of questionable cost–effectiveness. A clearer recommendation could help prevent inappropriate use of limited resources.

The following approach to reviewing and prioritizing the recommendations for updating was proposed:

- Priorities for the revision of recommendations should be based on countries' needs.
- A systematic, timely, defined process should be developed to identify recommendations for priority review and updating, where appropriate, of recommendations.
- The new processes should be linked to the new GMP policy processes, with clearly defined roles for stakeholders including NMCPs, WHO regions, WHO headquarters, the Guideline Review Committee, GMP and its advisory groups.

When modified guidance is implemented, evidence should be generated to assess its impact, which should be used in revising and strengthening future recommendations.

Adaptation of recommendations at country level is critical. Countries should adapt recommendations as necessary to set their own policies.

1.2 Users of guidance

GMP sought feedback from those responsible for interpreting and acting upon WHO malaria guidance in several ways. A portal was created on the GMP website during 2019 to solicit suggestions of recommendations that should be developed or reviewed. The portal was announced in the GMP newsletter (circulated to over 6000 individuals and organizations), and some stakeholders were alerted individually. The response was disappointing, as only two contributions had been received by the time of the meeting.

Three questions on individual WHO recommendations were sent to NMCP managers in advance of the current meeting:

- Which do you find difficult to act on?
- In what way could individual recommendations be changed to make them more useful?
- What guidance is missing or incomplete?"

The feedback received is summarized below.

Cameroon

Dr Dorothy Achu, NMCP Director, noted that not all recommendations apply to all countries and that dissemination of guidelines could be improved to increase awareness of GMP policies. In answer to the questions "Which do you find difficult to act on?" and "In what way could individual recommendations be changed to make them more useful?", she made the following comments.

- Use of LLINs: Distribution is quite wide (e.g. 77% LLIN ownership); however, only 50% of nets are used. Procurement policies and cost often prohibit the purchase of nets of preferred sizes, shapes, texture and other aspects.
- Use of quality-assured medicines: When the state health system is weak and attendance is low, many people go to private health facilities, which are less strictly regulated.
- SMC: Cameroon consists of diverse geographical areas, some having long (6 months) and others short (4 months) seasonal transmission. The WHO SMC recommendation covers only 4 months, so that some children in areas with slightly less intense seasonal transmission do not have access to the intervention, despite them carrying about 70% of the country's childhood mortality.
- Mass drug administration (MDA) is currently advised in four situations.[2] In Cameroon, requests for MDA have been received from areas in which the health system is not functional because of long-term insecurity. Nevertheless, MDA could be delivered by a nongovernmental organization if the current guidelines were updated to include such situations.
- Pregnant women (diagnostics and IPTp): IPTp coverage remains at about 50%. Pregnant women might benefit from IPTp delivered in the community, but SP is not permitted for use at community level in Cameroon. Another possibility is screening every pregnant woman, including in high-transmission settings; however, current policy guidance does not recommend this.
- Private sector: Many antimalarials are available on the market in Cameroon, and prescription practice varies widely, especially in the private sector. These limit the ability of countries to assure that people receive effective antimalarials at an appropriate dose and for a suitable duration and to monitor the quality of care in the private sector effectively.

In answer to the question "What guidance is missing or incomplete?", Dr Achu listed guidance on:

- when the malaria vaccine will be available;
- interventions at community level;
- working with and through the private sector; and
- operational research for national adaptation and formulation of policy, and funding for it.

In the ensuing discussion, it was noted that people were not using LLINs because of their size, colour and texture. The programme is constrained in their procurement choices and by its budget. The GFATM offered to fund a comparative study on various LLINs to determine whether use could be improved if certain net preferences were taken into consideration. A finding that procurement of more expensive nets resulted in more use, and thus "effective coverage", would be a rational basis for investing in the more expensive products. Consideration should be given to the impact of

[2] WHO currently recommends MDA for the interruption of transmission of *P. falciparum* malaria in areas approaching elimination; to reduce the risk of spread of multi-drug resistance in the Greater Mekong subregion; during malaria epidemics; and in exceptional complex emergencies *(2)*.

additional complexity on the supply chain and the ability of major funders to negotiate lower commodity prices.

United Republic of Tanzania

Dr Abdallah Lusasi and Dr Fabrizio Molteni said that the country's approach to allocating interventions is based on stratifying and targeting intervention packages at district level.

In answer to the questions "Which do you find difficult to act on?" and "In what way could individual recommendations be changed to make them more useful?", they listed the following.

- MDA: The current recommendation does not state clearly whether MDA can be used outside emergencies. It is a prescriptive recommendation and not conducive to implementation at country level.
- LLINs: Universal coverage is difficult to achieve. Various strategies have been used, including continuous distribution through schools and campaigns, which have been evaluated and shown to maintain good access and ownership of nets. In low-transmission settings, the NMCP is considering stopping mass campaigns and distributing nets at routine visits to reproductive and child health clinics and in primary schools.
- IPTp: Guidance is necessary on the drugs to be used and where IPTp should be implemented as transmission decreases. The threshold of malaria transmission below which IPTp-SP is no longer cost–effective has not been determined. In the 2018 national strategic plan, IPTp is being withdrawn in very low transmission areas, and alternative treatment options are being introduced. The NMCP is seeking guidance on risk mitigation after withdrawal of IPTp. Technical guidance is required on evidence-based therapeutic alternatives and innovative approaches to increase coverage.
- IPTi: In the 2018 national strategic plan, the NMCP introduced IPTi as a strategy for reducing the burden in high-transmission areas, with phased introduction, starting in the south-east of the country. The WHO policy does not define "moderate" or "high" transmission intensity. Technical guidance is required on alternative drugs for IPTi, alternative administration schedules and targeting the population after infancy (e.g. up to 18 months of age) to prevent severe anaemia and mortality.
- Noting that SMC is recommended in areas of high seasonal malaria transmission across the Sahel sub-region, the country is introducing SMC to reduce the burden in moderate- to high-transmission areas in which the seasonality is similar to that in Sahel countries. It is also conducting implementation research to evaluate SMC in this context. The NMCP is considering use of chemoprevention in schoolchildren, and technical guidance is required on the choice of drug, the effect in low-transmission settings and extending the target population to schoolchildren (current recommendations specify children aged 3–59 months, but children up to 15 years of age bear a significant burden of disease).

In answer to the questions, "What guidance is missing or incomplete?", they reported the following.

- The country is exploring IPT for schoolchildren, as it is unacceptable for a child to have a parasitaemia of 3000/µL. Despite a long history of chemoprophylaxis for schoolchildren in much of the malaria-endemic world, there is no current recommendation for this age group and therefore no financial support from PMI or GFATM. Technical guidance is required on the choice of drug, dosing frequency and approaches to increase effectiveness and coverage, especially in remote areas.

- The country is considering use of preventive therapy in areas with a high prevalence of anaemia and malaria infection.
- Sentinel surveillance is not supported by policy recommendations, including school malaria parasite surveys and malaria testing of pregnant women at antenatal visits.
- Mass screening and treatment and focal screening and treatment for malaria are not recommended as interventions for interrupting malaria transmission. Focal screening and treatment will be part of the country's response to complex emergency situations and outbreaks, and technical guidance is required on its use to reduce the burden and on the choice of drug.

India

Dr Avdhesh Kumar described the decrease in malaria incidence and deaths in India, including in the seven north-eastern states, which have been highly endemic for malaria but which have seen remarkable reductions. Currently, under the national strategic plan 2017–2022, India has stratified states into three categories: for elimination by 2020, 2022 and 2027. Intervention packages are stratified by county and state, with subnational elimination certification. The malaria workforce includes 700 000 "accredited social health activists", a cadre of community health worker.

In answer to the questions "Which do you find difficult to act on?" and "In what way could individual recommendations be changed to make them more useful?", Dr Kumar noted the following.

Case management:

- Guidance is required on the combined use of bivalent rapid diagnostic tests and microscopy in relation to elimination.
- Guidance is required on testing all fever cases in an elimination setting.
- It was noted that WHO-prequalified rapid diagnostic tests and artemisinin-based combined therapy are two to three times more expensive than others on the market.
- Guidance on the appropriateness of treatment with primaquine for < 14 days would be useful.
- Guidance is required on MDA in highly endemic areas.
- Guidance is required on G6PD deficiency in relation to elimination.
- Guidance is required on diagnostic practices in elimination settings where surveillance is reduced because there are few cases.
- Evidence is required to better understand how people with low parasitaemia contribute to transmission in low-risk settings.
- Simpler, more sensitive rapid diagnostic tests are required for use in the community.

Vector control:

- Guidance is required on double or joint use of IRS and LLINs in the same geographical area.
- Guidance on large-scale disposal of LLINs and packaging is required.
- Guidance is required on the effective duration and replacement frequency of LLINs, as many people do not use nets for the prescribed 3 years because of damage and degradation.
- In hot and humid areas, people do not use nets, and guidance is required on engaging the community to promote use in these circumstances.

Private sector engagement:

- Guidance is required on engagement with the formal and informal private sector to ensure alignment with national and subnational policies.

Operational considerations:

- Human resources: As elimination approaches, guidance should be provided on sustaining human resources in general and entomologists in particular.
- Guidance would be useful to support cross-border collaboration.
- Guidance is required on subnational certification and ensuring resources as the burden of disease decreases, in order to sustain and complete elimination.

Peru

In response to an e-mail from Dr Veronica Soto-Calle, general feedback was given on providing more options within guidance and at the same times more specific information on implementing an intervention. Generally, a more didactic format would be welcomed. Guidance is lacking in particular on generating local evidence to inform strategies, policies and funding requests. It was considered that some recommendations were made for the African context and are less applicable to Latin America.

The group recognized some tension between global policy and the local context, e.g. artemisinin-based combined therapy versus chloroquine and rapid diagnostic tests versus microscopy, in Latin America. The same may apply to the South-East Asia Region, which covers countries at the extreme ends of the malaria risk spectrum and where the adaptation of global guidance to local conditions is a major challenge.

1.3 “High burden to high impact” countries

“High burden to high impact” countries have completed a self-assessment questionnaire, which also invited them to list problematic policy recommendations. GMP is also making and taking other opportunities to engage with NMCPs, such as at an RBM sub-regional meeting in Lusaka, Zambia, being held in parallel with the current meeting, and interacting with the Malaria Policy Advisory Committee at their meetings.

Dr Abdisalan Noor, GMP Surveillance Team Leader, described “high burden to high impact”, which is a country-led response catalysed by WHO and the RBM Partnership to reignite progress in the global malaria fight, especially in high-burden settings. The four elements of response are: political will to reduce the number of malaria deaths; strategic information to drive impact; better guidance, policies and strategies; and a coordinated national malaria response. The presentation focussed on the strategic use of information to drive impact, describing how “high burden to high impact” countries decide on intervention mixes and prioritize mixes of interventions. The process includes epidemiological stratification, the use of mathematical models to optimise the targeted use of mixes of interventions and costing of national malaria strategic plans.

Issues encountered in implementation of WHO guidelines in “high burden to high impact” activities were presented. The higher malaria case fatality rate in low-transmission settings than in some high-transmission settings may have implications for malaria resource allocation. Increasing urbanization in Africa and increasing recognition of the challenge of urban malaria may compromise the validity of information on the efficacy and effectiveness of existing tools, most of which have been evaluated

only in rural areas. It was noted that the coverage of LLINs is systematically higher in urban than in rural areas, despite the well-documented lower risk of malaria in urban areas.

LLINs

The guidelines for malaria vector control advise that: "In areas with ongoing local malaria transmission – irrespective of both the pre-intervention and the current level of transmission – the scale-back of vector control should not be undertaken *(6)*. Universal coverage with effective malaria vector control of all persons in such areas should be pursued and maintained. In areas where transmission has been interrupted, the scale-back of vector control should be based on a detailed analysis that includes assessment of the receptivity and vulnerability, active disease surveillance system, and capacity for case management and vector control response." (p. xvii)

In "high burden to high impact" countries, there is increasing population movement to urban areas, where there is less malaria transmission. Models suggest that withdrawing nets from areas where the *P. falciparum* parasite rate was < 1% in 2000 would probably not result in increased transmission if a good level of case management was maintained. It is, however, politically difficult to reduce LLIN distribution in urban areas. Some countries are using "top-up" approaches in urban areas, but these have not been cost–effective; other countries have withdrawn campaigns in urban areas but maintain routine distribution. Flexible, operationally adaptable policies are required for urban settings.

Recommendation on piperonyl butoxide

WHO guidance (p. xvii) states that "Pyrethroid-PBO nets prequalified by WHO are conditionally recommended for deployment instead of pyrethroid-only LLINs where the principal malaria vector(s) exhibit pyrethroid resistance that is: a) confirmed, b) of intermediate level, and c) conferred (at least in part) by a monooxygenase based resistance mechanism, as determined by standard procedures"*(6)*. This recommendation is difficult to implement, because there are no reliable subnational measures of insecticide resistance and its mechanisms in most countries.

IRS

Current WHO guidance (p. xvi) calls for "delivering either ITNs or IRS at high coverage and to a high standard, rather than introducing the second intervention as a means to compensate for deficiencies in the implementation of the first intervention" *(6)*. Some countries are using IRS in areas of high LLIN coverage and high pyrethroid resistance, and others use IRS without LLINs in high-transmission settings to reduce the burden. Countries wishing to scale down IRS are given no clear pathway.

Larviciding

Laviciding is a supplementary intervention. The guidance (p. xix) states that "The regular application of biological or chemical insecticides to water bodies (larviciding) is recommended as a supplementary intervention in areas where high coverage with a core intervention has been achieved, where aquatic habitats of the principal malaria vector(s) are few, fixed and findable, and where its application is both feasible and cost-effective" *(6)*. There appears to be political will to implement this recommendation, and domestic resources are often available. Nevertheless, countries find it difficult to implement it and to track progress, as many do not have the appropriate geospatial and entomological surveillance tools or a robust evaluation framework.

Targeting of SMC

The following questions were raised in relation to the recommendation on SMC.

- How should countries that are not in the Sahel sub-region but which meet the currently applied thresholds of seasonality and burden target SMC?
- Is it appropriate to target older age groups as well as children < 5 years, e.g. up to 10 years?
- How should SMC be targeted in areas with significant transmission for > 4 months of the year?
- What are the criteria for withdrawing SMC?
- Should SMC be implemented only in areas with good access to diagnostic and treatment services?

IPTi

The requirement for data on the frequency of the *Pfdhps* mutation is a barrier to considering IPTi.

Discussants stressed the importance of guidance on stratification and on prioritizing interventions within and between strata.

1.4 Global Fund to Fight AIDS, Tuberculosis and Malaria

Dr Scott Filler, Malaria Team Lead, confirmed that the GFATM uses WHO norms and standards in making decisions on funding but has to use pragmatic solutions in the absence of guidance. The GFATM seeks to maximize the impact of allocated funding. It recognizes, however, that impact may be defined in different ways, such as in terms of morbidity and mortality reduction or national or regional elimination of malaria.

Dr Filler addressed several specific WHO policies. With regard to vector control, the recommendation for universal coverage of LLINs has increased coverage, saved countless lives, catalysed funding for malaria and brought together the malaria community. Use of ITNs in reducing malaria transmission is similar to the use of antiretroviral drugs to prevent HIV infection; in both cases, careful consideration is required before reducing investments to avoid any rebound in disease burden. The aim has been to achieve universal coverage of LLINs through a combination of mass campaigns and continuous supply systems, such as distribution at antenatal clinics. Once certain coverage is achieved, however, the costs of further increasing coverage rise non-linearly. Therefore, one of the GFATM's performance indicators is the number of nets delivered per country rather than the coverage attained.

Prioritization of individual interventions and packages of interventions, including new tools, must be done carefully. Guidance is required on when it may be appropriate to reduce investment in established interventions in different situations. The importance of urban malaria is increasingly recognized, and different packages of interventions may be required in urban and non-urban settings. Discussions should be held on how best to achieve universal coverage of the most effective packages of interventions in different subnational settings.

With regard to case management, access to good-quality care should be increased urgently, not only in the public sector but also at community level and in the private sector. Care in the private sector is often considered as secondary, but it should be addressed seriously, especially in settings where most care is provided by this sector. Discussion is required on policies for drug delivery strategies (e.g. chemoprevention, active case detection and response) and how best to capture data on confirmed cases wherever they arise. The policy on chemoprevention should be reviewed, and a policy on active detective of infection should be considered.

While products purchased with GFATM resources must be prequalified by WHO or approved by a stringent regulatory authority, countries can receive GFATM support for activities that are not strictly within the scope of WHO recommendations. Situations in which remedial action becomes necessary to increase coverage of mosquito nets should be avoided, as such approaches have been shown to represent inefficient uses of resources. A proposal to give antimalarial treatment to schoolchildren had been refused because of an inadequate evidence base.

1.5 President's Malaria Initiative

Dr Richard Steketee, Deputy Coordinator, explained that PMI is not only a funding agency but also provides technical support to countries. The USA makes investments in malaria of approximately US$ 750 million per year through the PMI and its contributions to the GFATM. The latter are matched 1:2 by others donors, and the GFATM then invests 33% of its resources in malaria control. PMI has existed for 14 years, indicating that the value of the investment is recognized both within and outside the USA. PMI investments must continue to be seen as maximizing value for money.

PMI operates in 27 countries, 24 of which are in sub-Saharan Africa and which include all the African "high burden to high impact" countries. Currently, 40% of PMI funds are spent on commodities such as nets, antimalarial drugs and IRS. PMI uses data to decide on the allocation of resources and supports countries in data collection and analysis, also recognizing the importance of improving procurement, supply and delivery practices. As new interventions for malaria control become available, PMI will explore how they can be used with existing tools and how evidence can be used to decide on their use in different settings. The new interventions must be considered in the context of standards of care and considered part of flexible use of alternative mixes of interventions. Problem-solving approaches will require enhanced management skills in malaria control programmes to ensure effective use of appropriate mixes.

Participants in the general discussion recognized that deprioritizing LLINs in certain situations could provoke an acerbic reaction, given the strength of the message about universal coverage and its enormous benefits. As control improves and heterogeneity in malaria risk emerges, however, mixes of interventions will be required, with probable differences in the optimal mixes of interventions used in different epidemiological settings. Data will be required to target the most appropriate packages of interventions to various settings in each country to maximize the use of resources invested in malaria control throughout the country. Considerable domestic investment is being made in larval control, the impact of which may be questionable in many settings. Clearer guidance on the use of larval control as compared with other strategies would help malaria control programmes to counter pressures to adopt this approach.

1.6 WHO departments

Reproductive Health and Research department

Dr Ian Askew, Director, described the maintenance of "living" guidelines for more than 400 recommendations, based on over 270 systematic reviews. In this way, the typical 18–24 months required for guideline development and update has been transformed into a set of guidelines that are continually updated with new evidence as it becomes available, removing lack of consistency in determining when guidelines should be updated. This requires continual surveillance of the literature and "living" systematic reviews that are updated as new evidence becomes available. An oversight group that generally meets virtually can thus readily see how new evidence might change the estimated size of an effect or the strength of a recommendation. The "living" approach includes systematic reviews, a guideline development group and channels for dissemination. The challenges

include adequate representation of women and communities in reviewing recommendations and use of other types of evidence, such as qualitative syntheses. The department is exploring the potential of machine learning to update databases automatically for rapid appraisal of new evidence.

The department follows the WHO guideline development processes and has a steering group, with external experts, that meets once a year to determine priorities. Members of guideline development group are drawn from a pool of 30–40 external experts, with additional expertise as required. The cross-departmental guideline steering group ensures interdependence with other departments and harmonization of policy-making.

In the discussion, the group recognized that changing a guideline incurs costs for dissemination and, potentially, retraining of health workers. Such costs might be considered when deciding to update a guideline.

Maternal, Newborn, Child and Adolescent Health department

Dr Anshu Banerjee, Director, summarized a survey of policies related to maternal, newborn, child and adolescent health, which was sent to 194 countries. Five of the questions related to malaria in children < 5 and 5–9 years old. Some 6500 policy documents were received and will be made available through the departmental web portal. He said that there is growing recognition that children aged 5–9 years bear an increasing proportion of the malaria burden, especially in settings where overall malaria control is improving; however, only half of the malaria-endemic countries that responded to the survey have malaria control policies that address this age group. This implies that age-targeted approaches and stratification of control should be undertaken. The vast majority (38/41) of malaria-endemic countries that implement Integrated Management of Childhood Illness in sub-Saharan Africa include malaria in the management algorithm. Of the 85% of countries in sub-Saharan Africa that have guidelines for community health workers, 64% include community management of uncomplicated malaria. A minority of countries had documents that refer to IPTi (7/35), SMC (12/34) or both (3/41). A notable finding was relatively good access to preventive interventions (80% for growth monitoring, 74% LLIN) but poorer access to case management (estimates up to a maximum of 50%). The survey was considered useful for understanding which policies are being adopted, although a distinction must be made between policy adoption and implementation.

HIV department

Dr Rachel Baggaley provided a series of examples of the provision of guidance in situations of limited evidence. She traced the evolution of guidance on pre-exposure prophylaxis, which started in 2012 as a conditional recommendation for use in demonstration projects. This was based on early trial data (with mixed results from an intention-to-treat analysis but a clear relation between efficacy and adherence) and recognised the need for implementation and evaluation to strengthen future guidance. Following a randomized controlled trial and data from “open-label extension”, the recommendation was progressively strengthened and extended to a series of target groups. For example, a strong recommendation was made in 2014 for such prophylaxis for men who have sex with men, but a conditional recommendation was retained for other subgroups and no recommendation for people who inject drugs. A decision in 2014 to not have a recommendation for people who inject drugs, despite a randomized controlled trial that demonstrated efficacy in this group, was based on the values and preferences of drug injectors’ networks at the time. Updates in 2015, 2016, 2018 and 2019 have strengthened and widened the recommendation to offer pre-

exposure prophylaxis to all people at substantial risk of HIV infection, including people who inject drugs.

Guidance on the drugs to be used for pre-exposure prophylaxis has also evolved. Although data from trials was available only for tenofovir alone (in trials only for heterosexual men and women and not for men who have sex with men) and for tenofovir–emtricitabine for all populations, the recommendation was for tenofovir-containing pre-exposure prophylaxis, allowing use of another combination (tenofovir–lamivudine). This was made to support access, as tenofovir–emtricitabine remained on patent in some countries. Indirect evidence from studies in experimental animals and on pharmacokinetics sufficed for listing of tenofovir–lamivudine on the WHO list of essential medicines.

Some guidance with a very weak evidence base includes that on when to start and stop pre-exposure prophylaxis, which is based on pharmacokinetic modelling and the regimen for post-exposure prophylaxis. No randomized controlled trials have been conducted of the efficacy of post-exposure prophylaxis. A case–control study in 1997 suggested that azidothymidine prevents acquisition of HIV if taken within 72 h of exposure, and its use rapidly became standard practice. It was then considered unethical to conduct a placebo-controlled trial, nor have any trials been conducted of the efficacy of different drug regimens. Nevertheless, countries subsequently used a combination of two and now three antiretroviral drugs on the basis of inferences from experience with treatment and prevention of mother-to-child transmission.

A recent more experience in HIV guideline development is related to dolutegravir. WHO is unifying the recommended first-line treatment regimen for all populations to ensure the most effective combination of antiretrovirals to maximize impact, facilitate delivery and simplify the supply chain. In 2018, emerging evidence led WHO to consider dolutegravir as part of first-line treatment, as it is a highly effective, well-tolerated antiretroviral. Evidence of a possible association with neural tube defects after use in the peri-conception period, however, led to a proposal to caution against use of dolutegravir in women of child-bearing age unless they were taking effective contraception. Community groups, particularly women living with HIV, however, expressed concern that the caution was an overly strict interpretation of the recommendation. Consultations, with the involvement of infected women, ensured a choice-based approach, including the availability and integration of effective contraception in HIV services, rather than a more directive approach. Although it may be more complicated for health care providers and programmes to provide a choice of antiretroviral regimens for women living with HIV, it allows women to make choices according to their preferences.

Quality, Norms and Standards department

Dr John Grove, Director, described the planned role of the new department. It will not only support guideline development at WHO but will also provide quality assurance for other WHO operational guidance, such as manuals and handbooks. The department will also support governance of technical advisory and guideline development groups. The use of information other than from randomized controlled trials is an area of interest, and a workshop has been convened to consider public involvement in guideline development; another addressed the identification and management of conflicts of interests; and a third workshop is being planned to consider the role of modelling.

2. Examples of policies

2.1 Universal coverage of insecticide-treated mosquito nets

For practical consideration of the challenges of reformulating policy guidance, two contrasting examples of existing guidance were considered.

Background

Dr Jan Kolaczinski, Coordinator of the Entomology and Vector Control unit at GMP, explained that the term "universal coverage" was first introduced into a WHO recommendation in 2007 and was included as an "implementation consideration" in the current vector control guidelines *(7, 8)*. The recommendation has had a significant impact. Between 2000 and 2015, an estimated 663 million clinical cases of malaria were averted, of which 68% were attributed to use of ITNs at coverage levels well below universal coverage *(8)*. The costs of pursuing universal coverage rather than a lower operational target must be weighed against the benefits of investing in alternative malaria control modalities. He noted that the evidence underlying the recommendation for universal coverage should be reviewed comprehensively and clarified.

Universal coverage of ITNs: the evidence

Professor Jo Lines, London School of Hygiene & Tropical Medicine, described how the recommendation for universal coverage of ITNs had been reached, which is also summarized in Table 1. The recommendation was predicated on the assertion that ITNs confer community protection; however, a community effect was clearly demonstrated in Ghana and the United Republic of Tanzania but not in Burkina Faso or The Gambia.[3] The reasons for the difference remain unclear but may reflect a different mode of action of nets in different settings. For instance, in Burkina Faso, the repellent effect of the impregnated materials was considered an important part of the mechanism of action. Elucidation of the reasons for differential effects has been complicated by discrepant findings from entomological studies (for instance, a reduction in the number of female *Anopheles* mosquitoes captured in pyrethroid-spray catches in The Gambia but no difference in the number caught through human landing catches).

The first WHO recommendation on wide-scale use of ITNs was delayed because of doubt about the generalizability of the recommendation to other settings, and the issue is not entirely resolved today for LLINs and many other interventions. The lack of a financing mechanism, the limited availability of nets and the absence of a means to deliver them to users might also have curbed enthusiasm to make an early recommendation.

[3] A community effect of ITNs was also documented in western Kenya *(9)*.

Table 1. WHO recommendations on use of ITNs for malaria control

	Trials of ITNs and LLINs	WHO recommendation
Before 1990	Promising entomological results: a few epidemiological trials with uncomplicated clinical outcomes	1992: Vector control hardly mentioned in the new Global Malaria Control Strategy; only "IRS for selective vector control"
1991	First trial in Africa with a reduction of > 50% in child mortality	1994: Vector control should be selective. ITNs acknowledged as an effective form of personal protection, but doubt expressed about generalizability; no wide-scale recommendation
1992–1996	Trials by TDR and the US Centers for Disease Control and Prevention of effect of 100% coverage on child mortality in settings with various transmission intensities	1996: "ITNs may be useful in public health" but still no wide-scale recommendation
1998	"ITNs as cost-effective as measles vaccine for child survival"	2000: ITN coverage targets proposed by newly launched RBM. Abuja targets focus on vulnerable groups Malaria is included in proposed "Global Fund for AIDS and Tuberculosis"
2004	Pilot study of mass distribution of free nets found intervention to be cost–effective and equitable.	RBM: "scaling up for impact": mass campaigns targeted mainly at children < 5 years and pregnant women
2007	Initial effect on child mortality was disappointing, assumed to be lack of a mass effect but there was continued low actual coverage of ITNs by children < 5 years	United Nations Secretary-General announces a target of universal coverage, not only for vulnerable groups. Mass campaigns extended to everyone. Impact improved.

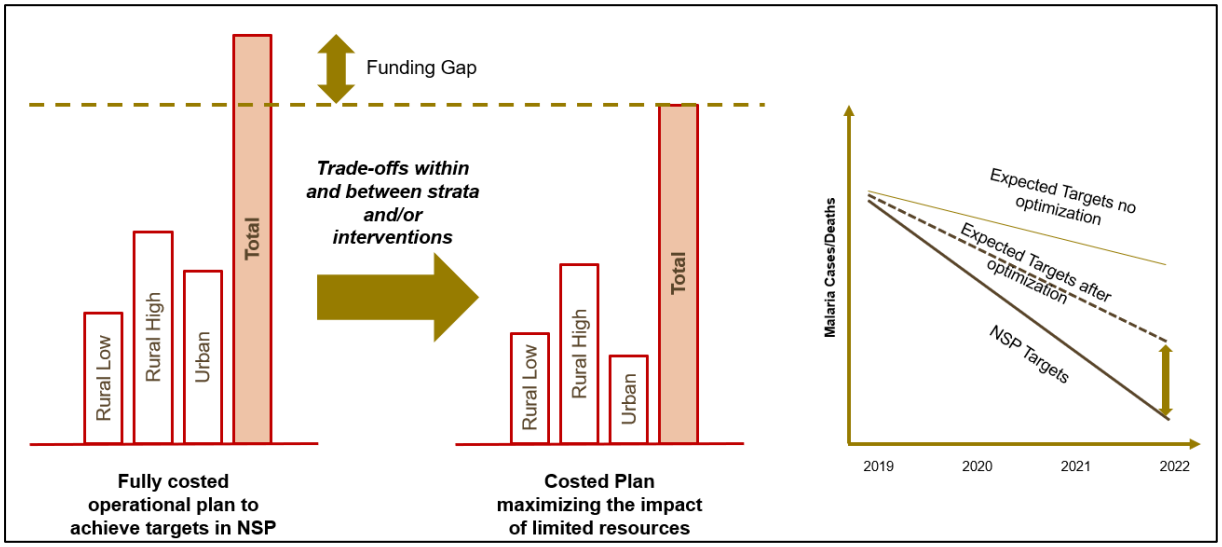
Challenges to maximizing impact in a resource-constrained environment

Bruno Moonen, Bill & Melinda Gates Foundation, noted that the scaling up of malaria interventions through more funding and decreases in the cost of interventions had resulted in an unprecedented reduction in incidence between 2000 and 2015. Nevertheless, overall access to and use of interventions remains suboptimal. The challenges described in the World Malaria Reports in 2017 and 2018 are exacerbated by population growth and the corresponding decrease in any given financial investment in malaria per capita. The prices of key commodities are expected to increase as next-generation tools are introduced to counter biological adaptations to insecticides and drugs and *HRP-2* gene mutations that threaten effective control. While the current approach has been extremely effective, he questioned whether the current input-driven approach would maximize impact in future.

A country that receives funding for universal coverage of LLINs faces substantial practical challenges in obtaining a reliable estimate of the target population, with a huge impact on the resources required. For example, the highest net coverage was achieved in urban areas, which had the lowest risk of malaria, while the coverage in rural areas was about 50%. The funds for urban coverage with

other interventions might perhaps have been used in areas at higher risk. The optimal mix of interventions should be defined for different epidemiological settings in a multi-dimensional exercise, to ensure that funds are allocated as efficiently as possible, as illustrated in Fig. 1.

Fig. 1. Definition of the optimal mix of interventions for different epidemiological settings



Source: Presentation by B. Moonen

WHO has not provided guidance on deprioritizing interventions such as LLINs and SMC. Consideration should be given to changing the approach to prioritization from one based on input to one based on outcome. The United Republic of Tanzania is a good example of a high-burden country that has shifted towards subnational tailoring through stratification, modelling, financial prioritization and targeted delivery.

2.2 Chemoprevention: criteria for implementation

With vector control, chemoprevention is one of the key approaches recommended by WHO for the prevention of malaria. Ms Maria Tusell described the three chemoprevention strategies recommended for protecting the most vulnerable populations, IPTi, SMC and IPTp. All three strategies involve administration of a course of antimalarial treatment to prevent infection. Table 2 lists the key elements of the three strategies in the most recent policy guidance.

Table 2. Elements of IPTi, SMC and IPTp chemopreventive strategies

	Target population	Transmission area	Where administered	When administered	No. of countries that have used intervention
IPTi (SP)	Infants	Areas of moderate-to-high malaria transmission in Africa	In routine vaccination schedule	All year	1

SMC (AQ + SP)	Children aged 3–59 months	Highly seasonal malaria transmission areas in the Sahel sub-region in Africa	Mass delivery campaigns	During 4 months of high transmission	12 No. of children eligible in 2017: 29.3 million; no. of children treated in 2017: 15.7 million
IPTp (SP)	Pregnant women	Areas of moderate-to-high malaria transmission in Africa	At each antenatal visit after 2nd trimester, 1 month apart; at least 3 doses during pregnancy	All year	39 Coverage of IPTp1, IPTp2 and IPTp3 in 2017, 54%, 42% and 22%, respectively

Current WHO recommendations on chemoprevention were presented and contrasted, with a comparison of the processes for policy development. The wording and levels of detail in the three sets of recommendations differ widely, as, for example, the targeted transmission areas for IPTi are "countries in sub-Saharan Africa", for SMC "Sahelian countries with highly seasonal transmission" and for IPTp simply "countries in Africa". Transmission intensity. The requirements for transmission intensity are also defined differently: "moderate to high transmission (EIR ≥10)" for IPTi; clinical attack rate of > 0.1 per transmission season in the target age group for SMC; and undefined "moderate to high transmission" for IPTp. The caveats also differ, such as the level of background resistance to the drugs: "prevalence of the Pfdhps 540 mutation of ≤50%" for IPTi, "SP + AQ remain efficacious (>90% efficacy)" for SMC and a statement for IPTp that there were insufficient data to determine the level of resistance at which IPTp should be discontinued. These differences in how the recommendations are stated may be due partly to differences in how and when the guidance was developed, as WHO policy-making processes have been evolving over almost 20 years.

It was noted that a similar comparison with MDA might indicate generalizable principles on the use of drugs to prevent malaria in endemic populations.

2.3 Discussion

The following points were raised in the general discussion.

Engagement of end users. Users must be engaged throughout the development of guidelines to avoid unnecessarily restrictive guidance.

Transferability of recommendations: Each recommendation will never feasibly be adjusted to all local contexts in which it might be useful. Practically, countries will make decisions according to the available information. The intervention should be clearly defined, as this affects the generalizability or "transferability" of a recommendation. A number of strategies are referred to as "interventions", including MDA, SMC, IPTp and IPTi, while all involve distribution of antimalarial medicines to individuals at risk but with unknown malaria infection status and with the aim of clearing any existing and preventing new infections. The differences are in the target group, the drugs and the approach for delivering them. Discussants questioned whether they are different interventions or different strategies to deliver basically the same intervention.

Transferability versus specificity: It may be difficult in WHO malaria guidance to balance specificity and generalizability. All the representatives of NMCPs at the meeting urged more transferable

guidance, while the Peruvian programme had requested more didactic recommendations. It was agreed that GMP should generally provide more transferable recommendations, on the understanding that they would be adapted regionally and nationally, as appropriate. The human resources required to ensure effective adaptation merit serious consideration. WHO is moving towards "living" guidelines, for which both implementation and the availability of new evidence should be monitored to determine whether the recommendations should be more or less specific and to identify barriers to implementation. Such a system would, for instance, have shown that IPTi is not being adopted and would have stimulated investigations.

Prioritization of resources: The participants discussed whether prioritization of resources should be considered when making recommendations or be included in operational guidance. WHO has no tool to support countries in prioritizing interventions; any such tool should be validated with empirical data. The group agreed that countries should be supported in using modelling to compare different scenarios and to explore any trade-offs associated with different mixes of interventions, within and between epidemiological strata. After adoption and application of the solution shown to be preferable in modelling, rigorous monitoring of changes in epidemiological parameters should then be recorded to strengthen the evidence base for decision-making. Prioritization, monitoring, evaluation and feedback should be part of a framework of systematic, standardized processes for selecting interventions. Appropriate technical human resources will be required for scaling up. Participants agreed that this approach is complex and will become more so in the future as new interventions (e.g. various vector control tools) become available.

A sense of urgency and a window of opportunity. As many NMCPs will be preparing concept notes for GFATM funding early in 2020, support for prioritization and modelling should be accelerated. The ideas being discussed should be circulated rapidly among NMCPs, donors and other stakeholders. With this in mind, the group prepared a statement for consideration by the Malaria Policy Advisory Committee at its next meeting *(3)*.

3. Evidence for policy and implementation

3.1 Transferability

Professor Kara Hanson, London School of Hygiene & Tropical Medicine, presented ideas on transferability developed by Catherine Pitt, a PhD candidate at the School. The work addressed the transferability of the cost–effectiveness of malaria interventions but is more broadly applicable. Transferability was defined as "the degree to which evidence regarding interventions in one context may be used to inform decisions regarding another context (either with or without modifications to the analysis or interpretation)". The issues of transferability include the fact that costs and cost–effectiveness may vary with input prices, epidemiology, demography, health system characteristics (both demand and supply) and any changes to the intervention itself (including to adapt the intervention to the local context). Secondly, robust evidence from an empirical evaluation is rarely available to inform the precise problem faced in making a decision. Thirdly, it is wasteful and inefficient to exclude evidence because it was not generated in exactly the same context for making the decision of interest and is likely to result in suboptimal policy choices.

Transferability can be considered as a spectrum in which an intervention is either not transferable, transferable with adjustment or transferable without adjustment. The latter case can be considered generalizability. Transferability depends on:

- understanding and communicating the intervention and how its components interact with each other and with the local context to change costs and effects;
- the similarity of key characteristics between the original and the target contexts; and

- understanding which of the contextual characteristics are critical, which depends on the intervention, its mechanisms of action and both the original and the new context.

Evidence should be generated and evaluated for context-specific decision-making, which should be based on understanding of the mechanisms of action, the original context of the evidence and the target context for the decision.

3.2 Non-randomized designs for evaluating impact

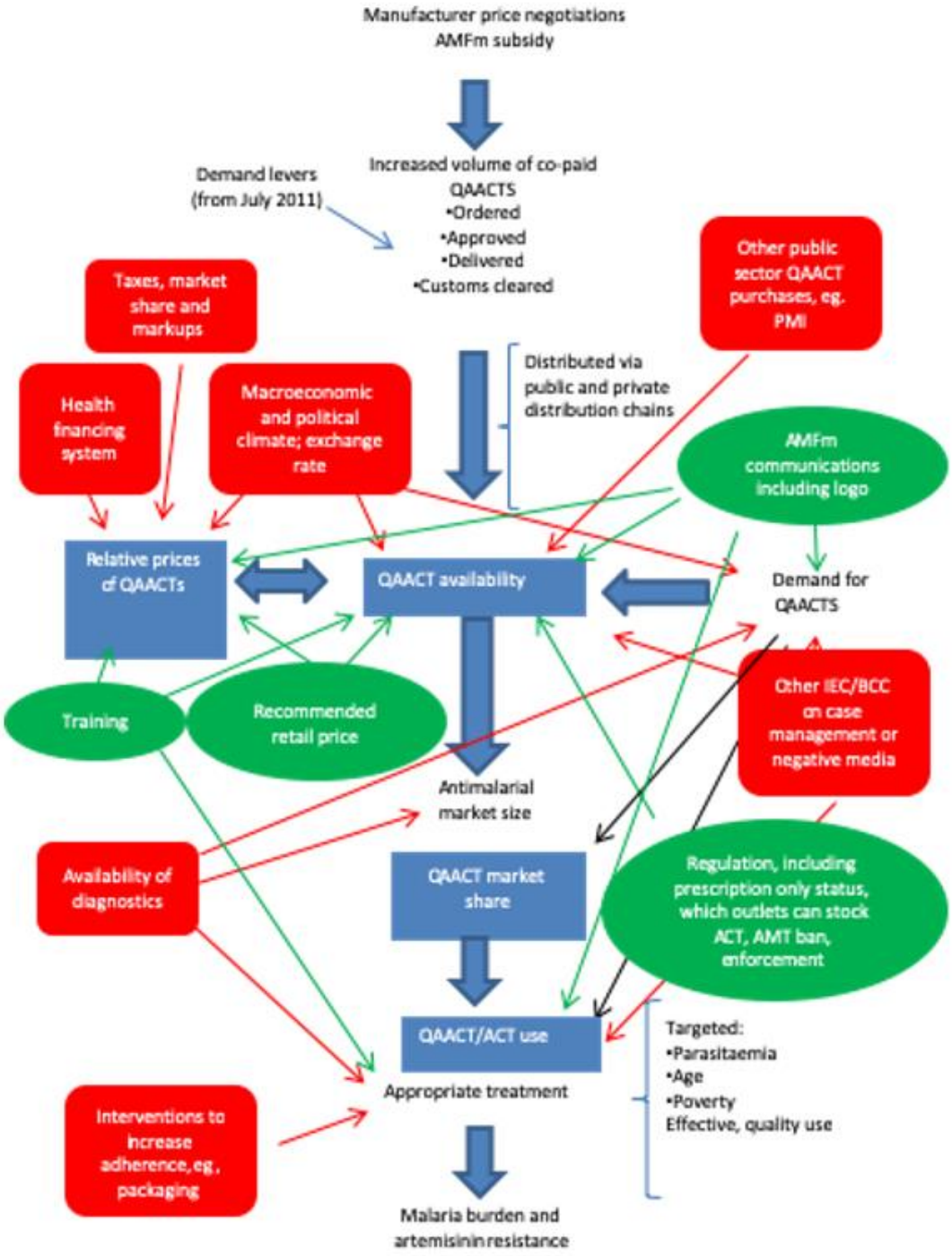
The "gold standard" evidence for guideline development is from randomized controlled trials, which provide statistical estimates of the probability that an intervention produces a certain effect. Alternative designs may be used, but they provide different levels of inference. For example, before-and-after studies have been referred to as "adequacy" designs, as the intervention may adequately explain any differences observed after its introduction. A design referred to as "plausibility" involves both a before-and-after comparison and a control area that does not receive the intervention to determine whether an effect was plausibly due to the intervention. Citing Davey C, et al., Professor Hanson noted that, "Broadly speaking, randomized trials control for confounding by design, whereas observational studies do so by analysis" *(10)*.

Professor Hanson briefly described the value of several designs and analytical approaches, including non-randomized controlled comparisons, interrupted time series, non-randomized stepped-wedge (phased implementation) and dose–response (implementation strength) approaches. In any non-randomized comparison, the strength of inferences can be increased by prospective documentation of the factors that determine allocation (e.g. areas with poor health or economic indicators) and measuring these indicators in areas that do and do not receive the intervention. Matching could be used to ensure a good comparison group or to use the data to adjust the analyses of effect. The analyses could be based on an assessment of the "difference in differences", but care should be taken to understand and, to the extent possible, account for factors that influence the outcome and change differently in the intervention and comparison groups.

Strengthening of routine health information systems may provide opportunities to use interrupted time-series methods to evaluate the impact of mixes of intervention. This approach, which was illustrated by an example, requires data at several times to assess the plausibility that an intervention has had a certain size of effect *(11)*. The difficulty in this approach is distinguishing the effects of other interventions that might have been introduced at the same time.

Inference can be greatly strengthened by use of a conceptual framework or "theory of change" that indicates a priori how an intervention is expected to have an effect. A "process analysis", with mixed quantitative and qualitative methods, can be used to monitor the steps along a causal pathway to indicate the extent to which the effect is influenced by each step and identify where the pathway broke down if the strategy did not have its intended consequences. The principles are illustrated in Fig. 2. Development and evaluation of a conceptual framework could provide important support in the development of transferable recommendations.

Fig. 2. Theory of change used to guide interpretation of data collected in an independent evaluation of the Affordable Medicines Facility – Malaria.



Source: Presentation by Professor K. Hansen

ACT, artemisinin-based combined therapy; AMFm, Affordable Medicines Facility – Malaria; AMT, artemisinin monotherapy; IEC/BCC, information, education and communication/behaviour change communication; QAACTS, quality-assured ACTs

The blue boxes indicate the main outcomes measured; the green ovals represent "supporting interventions" implemented with the price subsidy; the red boxes are contextual factors that may have influenced the relation between the programme inputs (subsidy and supporting interventions) and the outcomes.

In the ensuing discussion, it was agreed that use of other forms of evidence should be explored in preparing recommendations, as should tools (e.g. ROBINS-I) for evaluating the risk of bias in non-randomized studies. Although Cochrane reviews are powerful, the fact that meta-analyses do not take into account the complexity of context and the heterogeneity of complex interventions is an important limitation for the development of transferable recommendations.

4. Group work

4.1 Opportunities to reformulate guidance for solving problems in malaria control

Participants: Dr Dorothy Kah Fosah Epse Achu, Dr Avdhesh Kumar, Dr Abdallah Lusasi, Dr Fabrizio Molteni, Dr Richard Steketee, Ms Maria Tusell (Rapporteur) and Dr Anna Bowman.

The group was asked to discuss and identify WHO recommendations that are priorities for clarification. The working group also identified several areas in which further operational guidance is necessary.

The NMCP managers were asked to comment on three questions with regard to individual WHO recommendations.

- Which do you find difficult to act on?
- How could recommendations be changed to make them more useful?
- What guidance is missing or incomplete?

They replied that, generally, more guidance is required about when to stop some interventions.

For **vector control**, they requested the following recommendations and operational guidance:

- ITNs
    - Recommendations:
        - global guidance restricting the use of untreated nets;
        - guidance on thresholds for sufficient coverage of vulnerable groups.
    - Operational guidance:
        - to maximize net usage, as some people do not use them because of issues with the type, colour, texture, size and shape;
        - on prioritizing net distribution by stratification rather than trying to attain universal coverage.
- IRS
    - Recommendation:
        - Clarify when it is preferable to use IRS rather than ITNs and vice versa.
- Larviciding
    - Recommendation:
        - The current recommendation is for application of larvicide to aquatic habitats of the principal malaria vector(s) that are “few, fixed and findable”. Users found this term too vague and requested further clarification is required.
    - Operational guidance:

- Where, when and how to conduct targeted larviciding.

For **diagnosis:**

- Recommendations
  - when to use highly sensitive diagnostic tests;
  - advice on focal screening and treatment of high-risk groups for malaria (e.g. in refugee camps, epidemics).

For **treatment:**

- Recommendation
  - The recommendation on treatment during the first trimester of pregnancy is difficult to implement in many settings, and advice on the use of artemisinin-based combined therapies in the first trimester of pregnancy is awaited.
- Operational guidance:
  - on how to ensure that the private sector complies with guidelines.

For **preventive therapy**

- Recommendation:
  - on chemoprevention for people living in endemic countries who are probably not immune to malaria when travelling from areas with no or low transmission to places with significant risk of transmission.
- SMC:
  - Recommendation:
    - Revise the recommendation to include age, seasonality, where the approach can be used, methods of distribution and choice of drug.
- IPTp:
  - Recommendation:
    - Consider providing guidance on alternative drugs.
  - Operational guidance:
    - advice on alternative channels of distribution to increase coverage.
- IPTi:
  - Recommendation:
    - Consider increasing the age group up to 2 years.
  - Operational guidance:
    - on surveillance in border areas, including testing in areas of high endemicity, and how external funding can be used in such settings;
    - on the use of molecular markers of drug resistance to guide implementation.

Feedback from the RBM sub-regional (East and Southern Africa) meeting

The above questions were also addressed to the parallel meeting of NMCP managers from East and Southern Africa in Lusaka, Zambia. David Schellenberg addressed the meeting via Skype and

provided a summary of the discussion that followed his presentation, and Melanie Renshaw summarized the priorities that had been identified at the meeting.

The group confirmed that the generic guidance provided by WHO is adapted for use at country level but that adaptation takes time, contributing to the lag between the elaboration of global policy and implementation in countries.

The following recommendations were flagged for review and clarification:

- definition of transmission foci and recommended approaches for identifying and eliminating them;
- use of MDA by fragile health systems;
- use of SMC in 5–10-year-old children and beyond the Sahel;
- availability of next-generation mosquito nets; and
- use of rectal artesunate in emergencies.

It was noted that deviations from existing policy should be controlled and rigorously evaluated in order to strengthen the evidence base for future recommendations.

4.2 Principles of generalizability and requirements for evidence

The participants were: Professor Azra Ghani, Professor Kara Hanson, Dr Larry Slutsker, Professor Jo Lines, Dr Philip Welkhoff, Professor Dyann Wirth and Mr Philippe Verstraete (Rapporteur). They were asked to consider the principles for considering the transferability of evidence and the resulting recommendations and made the points listed below.

- Guidance should provide flexibility to ensure positive outcomes while preventing harm.
- Safety is paramount and should be considered first.
- A “toolbox” of guidance for generating evidence of the impact of interventions that have been modified or implemented in different settings would be useful. Both experimental and non-experimental designs would benefit from application of the theory of change to understand better the mechanism of action and the potential influence of contextual factors. This would contribute to understanding the transferability of evidence and any resulting recommendations to settings other than those in which the evidence was generated.
- The way in which PICO questions are formulated strongly influences the specificity and potential transferability of the recommendations that result. A hierarchy of PICO questions might be considered, in which a high-level question is followed by more granular sub-questions on contextual aspects. This could result in recommendations that are shorter, simpler and ensure that each component is qualified by the strength of the available evidence.
- The wording of global recommendations should be nuanced, especially with regard to stratification or cost–effectiveness, to distinguish between the mechanism of action (in the main recommendation) and operational aspects (which drive cost–effectiveness and would be part of the country’s problem-solving approach). Cost–effectiveness is a key consideration in deciding to adopt a recommendation at national or subnational level. Nevertheless, the drivers of cost–effectiveness (such as prices of commodities and coverage achieved) vary with time and place. To ensure transferability and uptake, the drivers of cost–effectiveness (e.g. a minimum disease rate) should generally not be included in a recommendation.

- Guidance should indicate the potential for operational stratification, consistent with the mechanism of action and theory of change, and draw attention to contextual factors that may lead to a decision not to pursue implementation.
- The way in which thresholds are framed can have a marked impact on the uptake of a recommendation. For instance, the requirement to demonstrate that molecular markers of resistance are below a certain threshold before adopting an IPTi policy is a strong impediment to implementation. Any such thresholds should have a strong empirical basis.
- Multiple thresholds or conditions should be avoided, as far as possible. When this is unavoidable, the relative importance of the different thresholds should be clear and guidance provided for situations in which not all the criteria are met.
- Ensure that the differential age patterns of malaria morbidity and mortality are considered in guidance on potentially age-targeted interventions.
- Provide advice on the data to be collected during implementation of a guideline to inform future reviews of recommendations. This implies the availability of a theory of change as a basis for monitoring.
- In general, the closer an end-point is to the biological point of action of an intervention, the more generalizable the outcome is likely to be. In contrast, downstream public health measures of impact, such as deaths averted, are likely to be heavily modulated by contextual factors (e.g. health-seeking behaviour, access to quality-assured health services and coverage achieved with a particular delivery mechanism). Such operational and contextual factors should be included in the theory of change and monitored during implementation.

5. Proposed next steps

It was agreed that Dr Richard Steketee, Chair of the meeting, would report to the Malaria Policy Advisory Committee on the outcomes of the meeting and seek endorsement of the statement prepared *(3)*. A commonly mentioned topic for review is chemoprevention, and a consultation is planned for mid-October 2019.

The observations contained in this report should be considered by the GMP when it revises its approach to guidance for Member States.

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2. Compendium of WHO malaria guidance – prevention, diagnosis, treatment, surveillance and elimination. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/312082, accessed June 2020).
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11. Ashton RA, Bennett A, Al-Mafazy AW, Abass AK, Msellem MI, McElroy P, et al. Use of routine health information system data to evaluate impact of malaria control interventions in Zanzibar, Tanzania, from 2000 to 2015. Eclinicalmedicine. 2019;12:11–9.

Annex 1. Agenda

Chairperson: Dr R. Steketee

Tuesday, 17 September 2019		
9:00–9:15	Welcome and opening remarks	P. Alonso
9:15–9:30	Meeting objectives	D. Schellenberg
Session 1: Perspectives on existing policies		
9:30–10:00	Review of existing GMP policies	L. Slutsker
10:00–10:40	Views from the field - Cameroon - United Republic of Tanzania - India - Peru	 D. Achu F. Molteni, A. Lusasi A. Kumar V. Soto-Calle
10:40–11.00	Early experience from "high-burden to high-impact" countries	A. Noor
11:15–11:25	Views of GFATM	S. Filler
11:25–11:35	Views of PMI	R. Steketee
	Policy examples from other WHO departments	
11:35–11:45	Maternal, Newborn, Child and Adolescent Health	A. Banerjee
11:45–11:55	Reproductive Health and Research	I. Askew
11:55–12:05	HIV	R. Baggaley
11:55–12:30	Discussion	Chair
Session 2: Example 1 Universal coverage of ITNs		
13:30–13:45	Universal coverage of insecticide-treated mosquito nets (ITNs): background	J. Kolaczinski
13:45–14:30	Universal coverage of ITNs: the evidence	J. Lines
14:30–14:50	Challenges to maximizing impact in a resource-constrained environment	B. Moonen
14:50–15:15	Discussion	Chair
Session 2: Example 2. Chemoprevention criteria for implementation		
15:45–16:30	From evidence to policy: the examples of SMC, IPTp and IPTi	M. Tusell
16:30–17:30	Discussion: considerations in reformulating policy • Generalizability of evidence from trials • Risks and benefits: off-label drug use • Moving from one-size-fits-all to a problem-solving approach	All, with invited comments from J. Grove
Closure of day 1		

Wednesday, 18 September 2019		
Session 3: Evidence for policy and implementation		
9:00–9:10	Plan for the day	Chair
9:10–9:40	Non-randomized designs for evaluating impact	K. Hanson
9:40–10:00	Discussion	Chair
10:00–10:15	Introduction to group work	D. Schellenberg
Session 4: Group work		
10:45–12:15	Group work: 1. Specific opportunities to reformulate guidance to support problem-solving approaches in malaria control 2. Principles in generalizability and evidence needs	
Session 5: Feedback from group discussions		
13:15–13:45	Presentation of working groups' outputs	Working groups
13:45–14:45	Consensus building	Chair
15:15–15:30	Summary of points of agreement	Chair
15:30–15:45	Proposed next steps	Chair
15:45–16:00	Closing remarks	P. Alonso

Annex 2. Participants

Chair

Dr Richard Steketee
Deputy Coordinator, President's Malaria Initiative, Washington DC, United States of America

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Professor Jonathan Lines
London School of Hygiene & Tropical Medicine, London, United Kingdom

Professor Lucy Paintain
London School of Hygiene & Tropical Medicine, London, United Kingdom

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Philippe Verstraete
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Professor Dyann Wirth
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Dr Avdhesh Kumar
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WHO Secretariat

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Dr Abdisalan Noor
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Dr John Reeder
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Dr Maru Weldedawit
Scientist, Surveillance, Global Malaria Programme

Update on the informal consultation: reformulating malaria policy guidance

Malaria Policy Advisory Committee

Geneva, Switzerland

Richard Steketee

3 October 2019

Global **Malaria** Programme

World Health Organization

Objectives of the informal consultation

Convened in Geneva, Switzerland on 17-18 September 2019 to **reconsider the formulation of malaria policy guidance.**

Participants included:

- end users of GMP guidance from NMCPs,
- GFATM, Gates Foundation and PMI
- academics and researchers
- WHO advisers

Objectives

- To explore how policy recommendations from WHO guideline development processes can be reformulated to:

  increase generalizability/transferability, and

  support problem-solving approaches in malaria control.
- Consider specific examples to **explore the need for and feasibility of reformulating malaria policy recommendations**.
- Articulate **principles to guide the formulation** of malaria guidance.

Background to the meeting

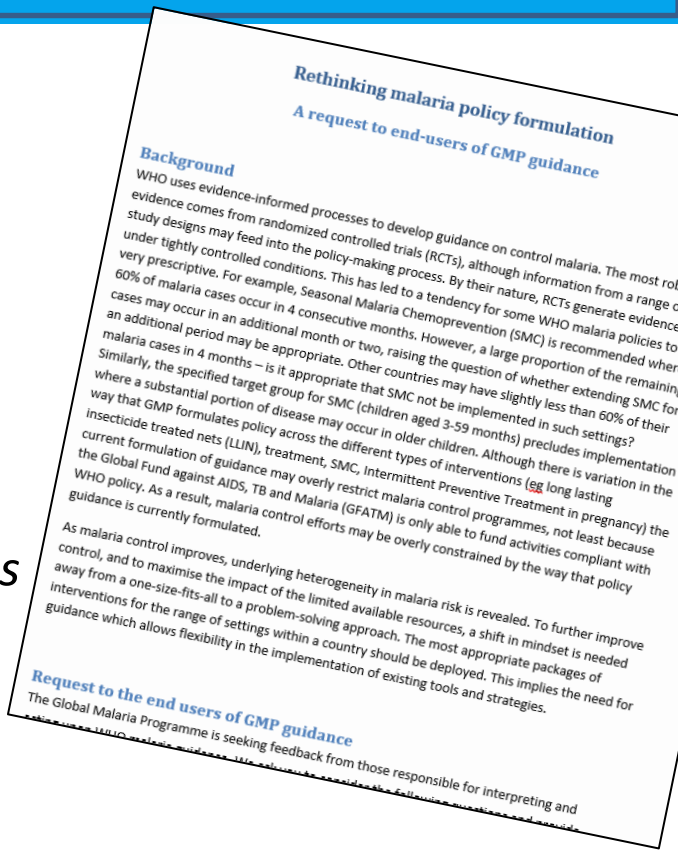
- WHO uses evidence-informed processes to develop guidance
- Most robust evidence comes from randomized controlled trials (RCTs)
  - Information from other study designs is considered
- RCTs done in tightly controlled conditions
  - Tendency for guidance to focus on situations in which evidence is available
  - E.g. Seasonal Malaria Chemoprevention (SMC) –
    - 60% of malaria cases in 4 consecutive months; Children aged 3-59 months
- Impossible to study all relevant questions in all relevant settings
- Are there situations in which WHO should support countries to move beyond the immediate evidence?
  - If so, when? And how?

Request to the end users of GMP guidance

The Global Malaria Programme is seeking feedback from those responsible for interpreting and acting upon WHO malaria guidance

Consider the individual WHO malaria recommendations

- *Which do you find difficult to act on?*
- *How could individual recommendations be changed to make them more useful?*
- *What guidance is missing or incomplete?*



Rethinking malaria policy formulation

A request to end-users of GMP guidance

Background

WHO uses evidence-informed processes to develop guidance on control malaria. The most rob
evidence comes from randomized controlled trials (RCTs), although information from a range o
study designs may feed into the policy-making process. By their nature, RCTs generate evidence
under tightly controlled conditions. This has led to a tendency for some WHO malaria policies to
very prescriptive. For example, Seasonal Malaria Chemoprevention (SMC) is recommended wher
60% of malaria cases occur in 4 consecutive months. However, a large proportion of the remainin
cases may occur in an additional month or two, raising the question of whether extending SMC for
an additional period may be appropriate. Other countries may have slightly less than 60% of their
malaria cases in 4 months – is it appropriate that SMC not be implemented in such settings?
Similarly, the specified target group for SMC (children aged 3-59 months) precludes implementation
where a substantial portion of disease may occur in older children. Although there is variation in the
way that GMP formulates policy across the different types of interventions (eg long lasting
insecticide treated nets (LLIN), treatment, SMC, Intermittent Preventive Treatment in pregnancy) the
current formulation of guidance may overly restrict malaria control programmes, not least because
the Global Fund against AIDS, TB and Malaria (GFATM) is only able to fund activities compliant with
WHO policy. As a result, malaria control efforts may be overly constrained by the way that policy
guidance is currently formulated.

As malaria control improves, underlying heterogeneity in malaria risk is revealed. To further improve
control, and to maximise the impact of the limited available resources, a shift in mindset is needed
away from a one-size-fits-all to a problem-solving approach. The most appropriate packages of
interventions for the range of settings within a country should be deployed. This implies the need for
guidance which allows flexibility in the implementation of existing tools and strategies.

Request to the end users of GMP guidance

The Global Malaria Programme is seeking feedback from those responsible for interpreting and

Transferability:

the degree to which evidence from interventions in one context may be used to inform decisions in another context

(with/without modifications to the analysis or interpretation)

The transferability spectrum

Not transferable

Transferable with adjustments*

Transferable without adjustments* (generalizable)

*"Adjustments" may be quantitative or qualitative, ranging from simple to complex (as described by Barbieri et al. 2010)

Themes & key points from the discussions

- *Problem-solving approach*
- *Leveraging existing flexibilities*
- *Intervention mixes*
- *"Living" guidelines and processes*
- *Reformulating recommendations*
- *Dissemination/deployment of guidance*

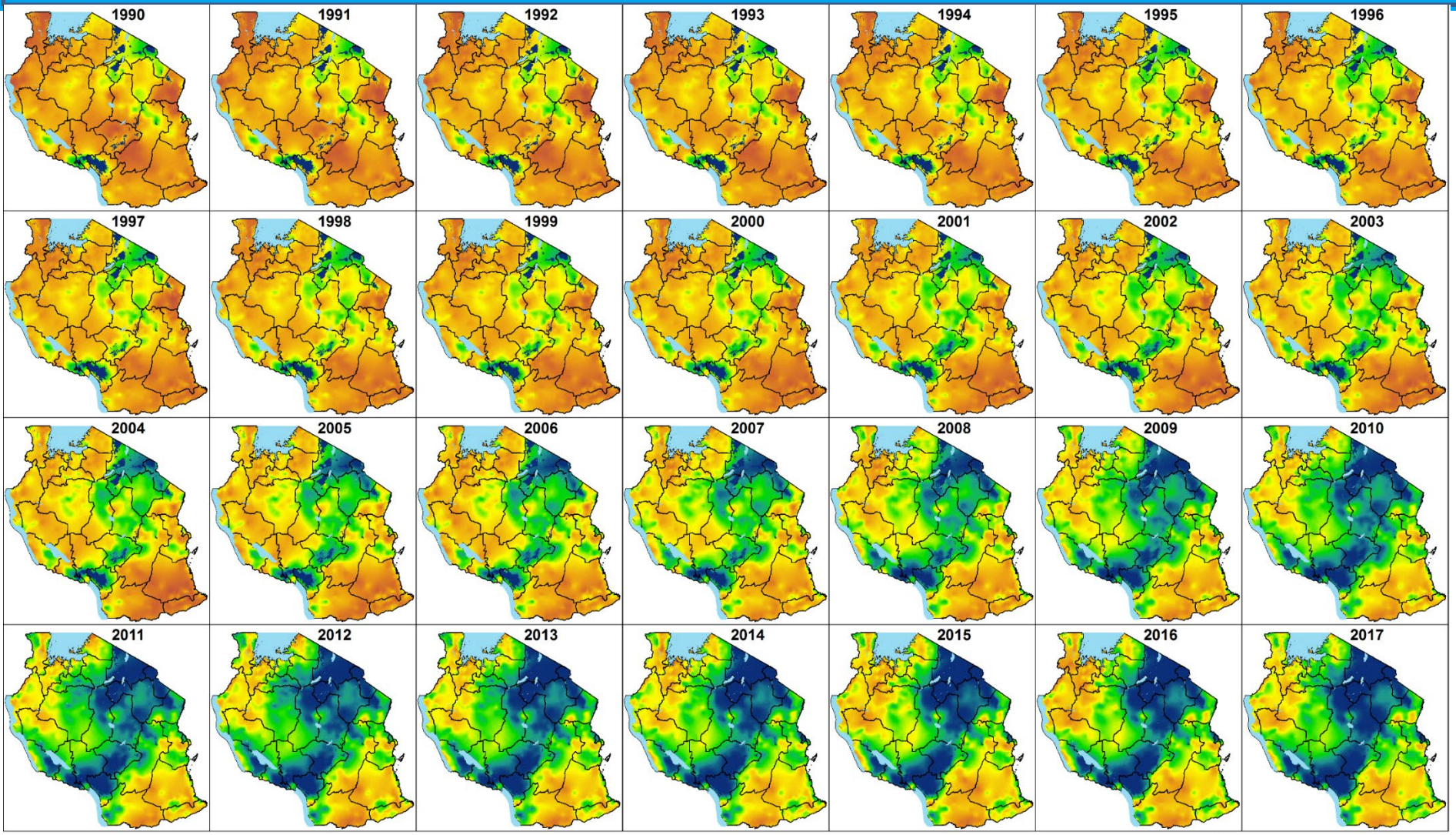
Problem-solving in malaria control & elimination

- As malaria control improves, underlying heterogeneity in malaria risk is revealed
- To continue to improve and to maximise the impact of limited resources, a flexible problem-solving approach must emerge to address the heterogeneity
- Deploy the most appropriate packages of interventions for the range of settings within a country
- Need guidance which fosters flexibility in the implementation of existing tools and strategies

Leveraging existing flexibilities

- Policy developers can leverage a range of evidence types during guideline development
- Countries can leverage existing operational (« How-to-do ») documents that complement guidelines and recommendations
- Countries can leverage flexibilities in funder policies and practice

Tanzania: Heterogeneity and intervention mixes



Mean *pfpr* 1990-2017 (NMCP, KEMRI Welcome Trust, 2018)

Global **Malaria** Programme

World Health Organization

RHR, HIV and MNCAH departments shared perspectives

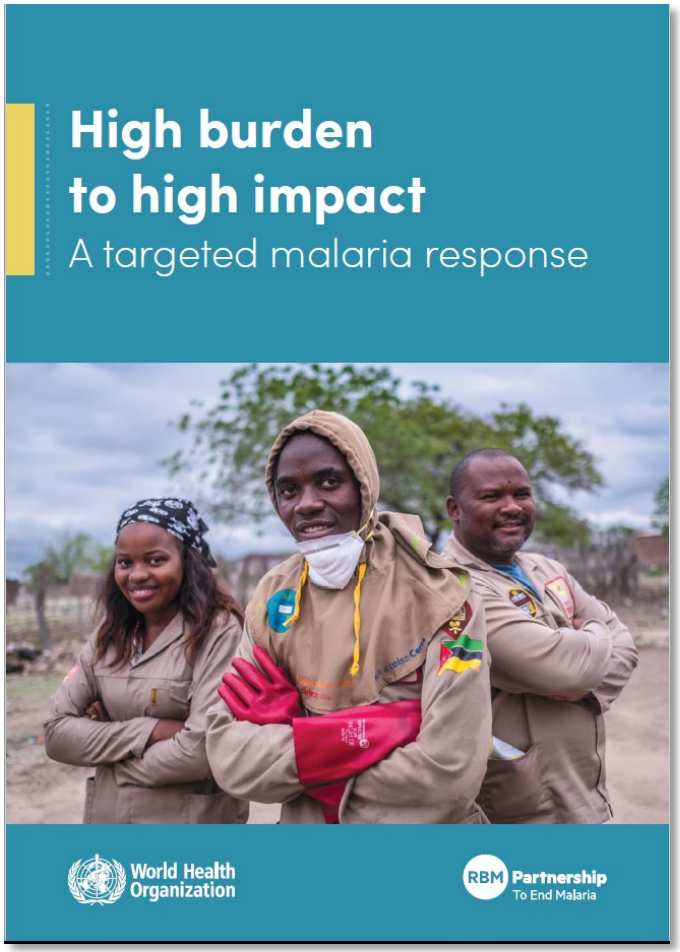
Box 3 Elements necessary for producing living recommendations

- Living systematic review
- Living Evidence Profile
- Living Evidence to Decision (EtD) table
- Living guideline panel
- Living peer review process
- Living publication and dissemination
- Living budget

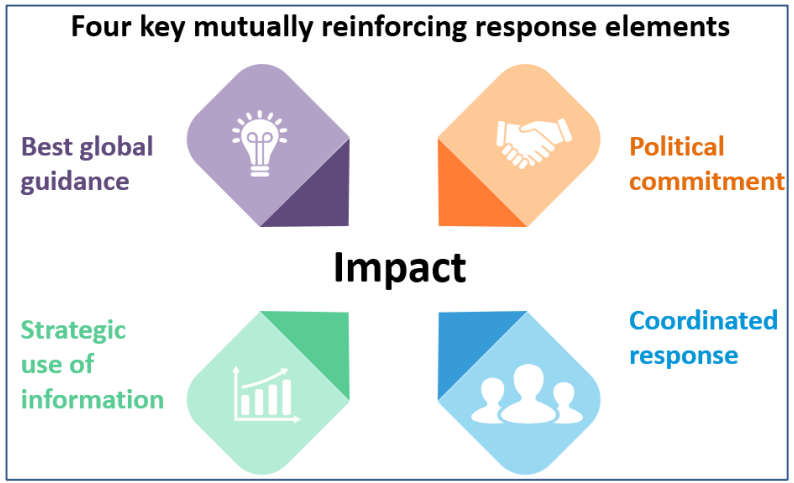
… "living" prioritization processes
… "living" technical working group

Akl E et al. Living systematic reviews: 4. Living guideline recommendations. Journal of Clinical Epidemiology 91 (2017) 47e53

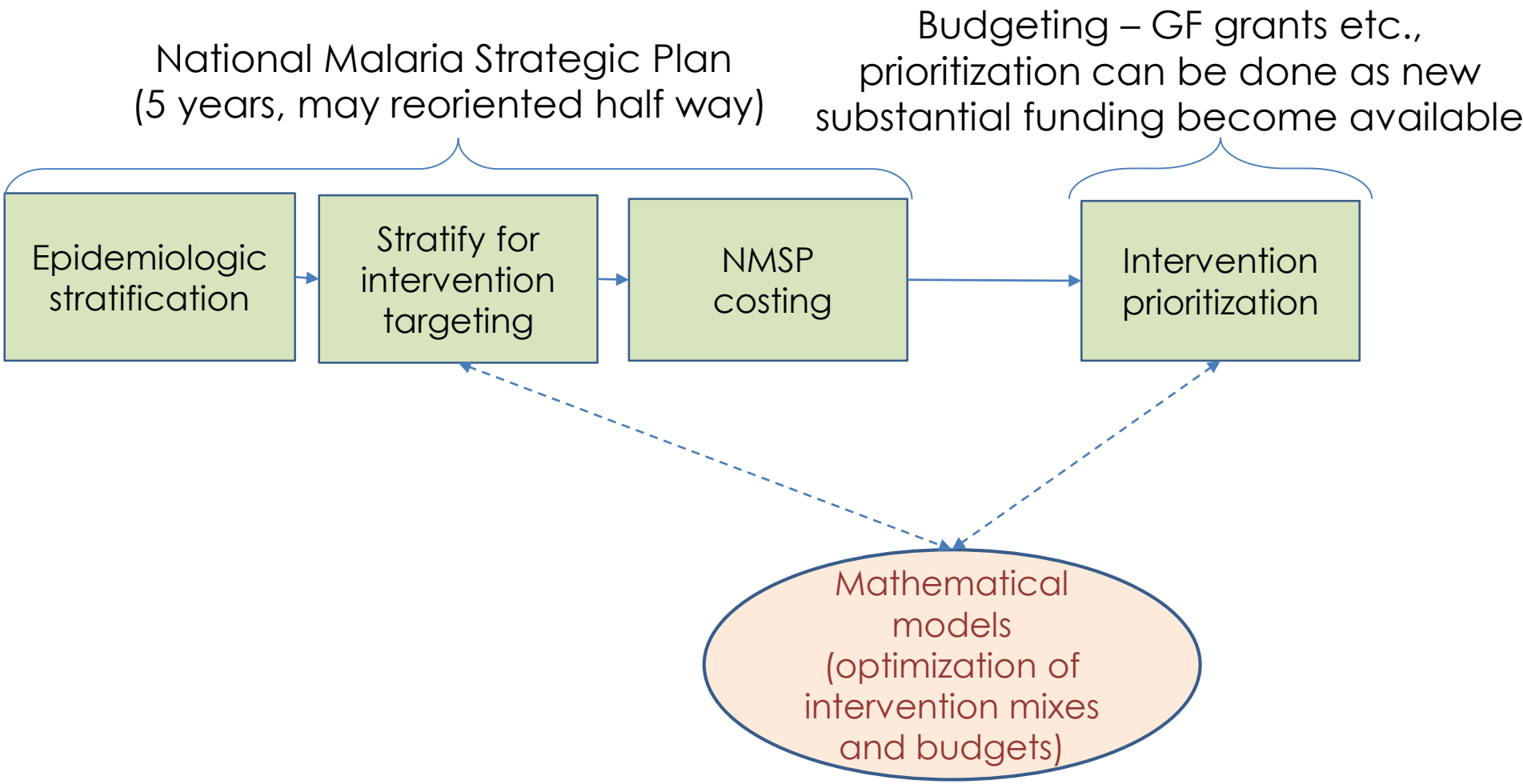
Supporting countries : HBHI example



- New response launched by WHO and RBM Partnership at high-level event in Maputo (Nov 2018)
- Initial focus on the 10 + 1 highest burden countries
- Lessons learned will be applied to other countries with a high burden of malaria



HBHI – intervention mixes and prioritization



Outcomes of the informal consultation

- Common themes emerged including identifying recommendations for early review
- Principles to apply when considering modifying / broadening existing recommendations or developing new recommendations which extend beyond available evidence
- Consensus statement

Consensus Statement

Document is available

Rationale

- Countries are already stratifying
- Different intervention mixes are likely needed in different strata within countries to maximise impact of available resources

Excerpt from statement

- **Intervention prioritization should not be driven solely by sequentially optimizing single interventions for maximal coverage;**
- **Instead, intervention prioritization should be based on local evidence and aligned to the specific needs of different epidemiological strata/settings as defined in the country's NSP**

Getting malaria control back on track

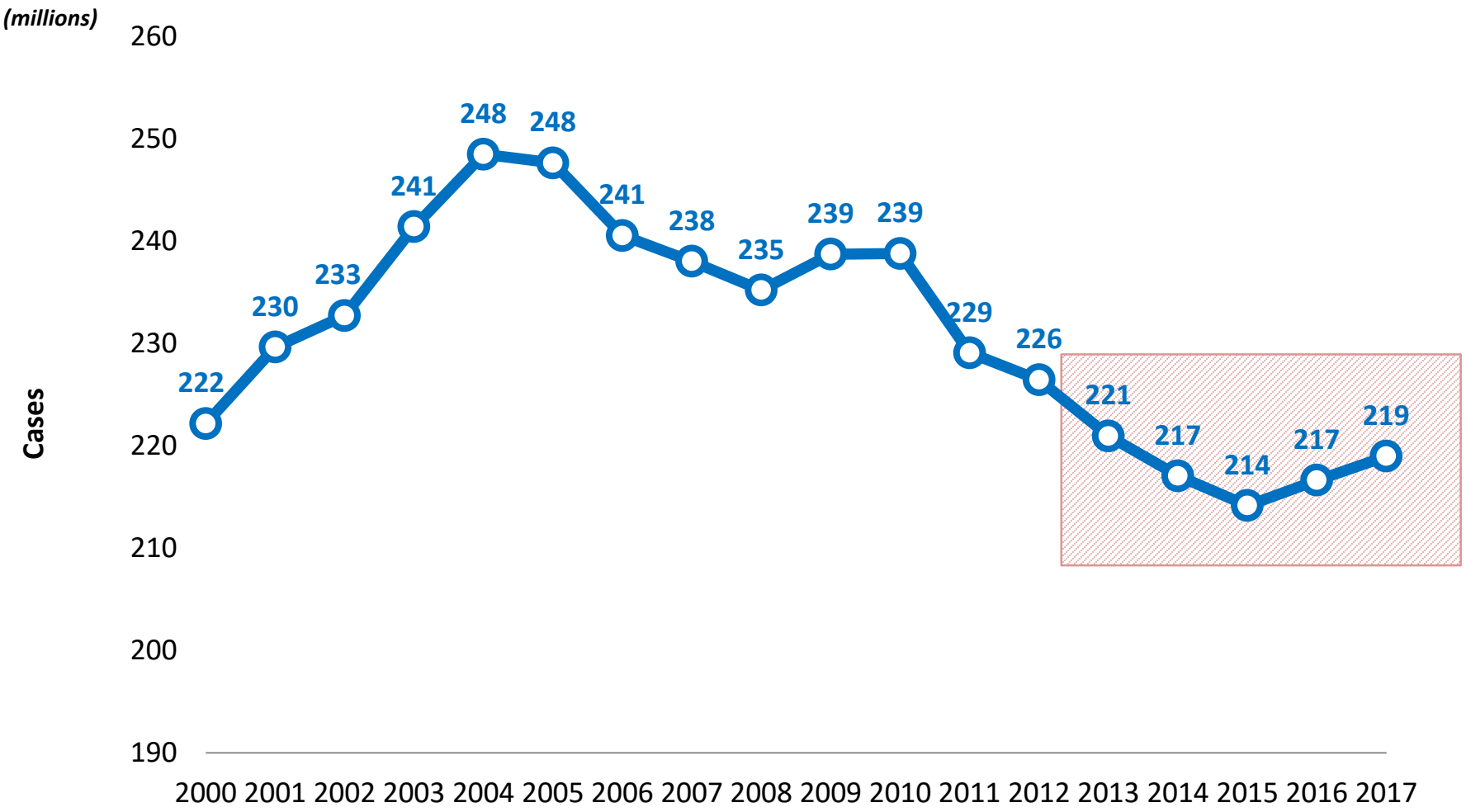
Making chemoprevention contribute

3rd October 2019 Geneva

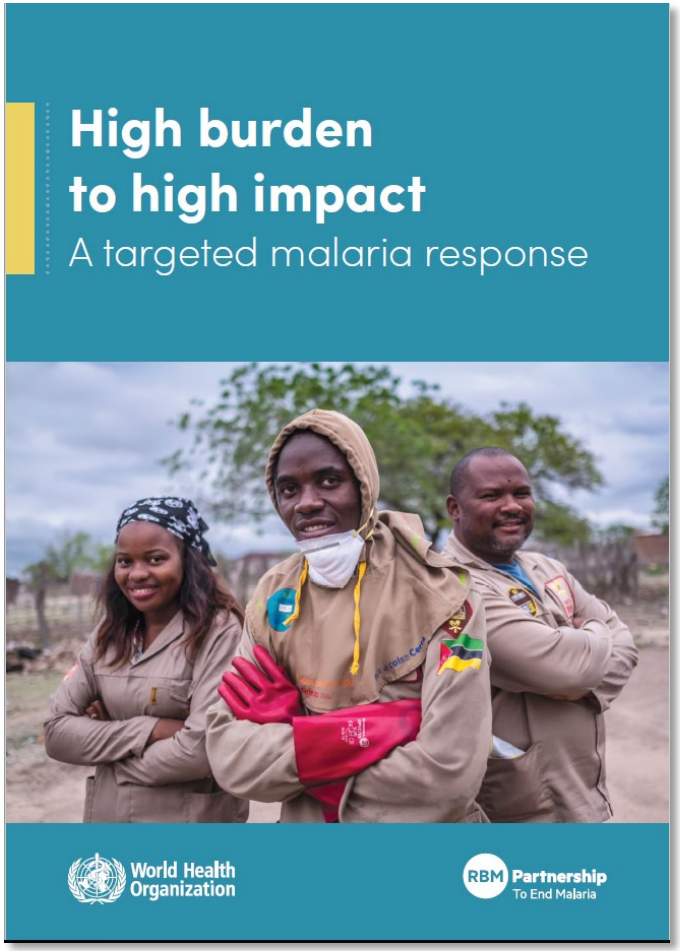
Global **Malaria** Programme

World Health Organization

Number of malaria cases worldwide, 2000–17



Getting back on track



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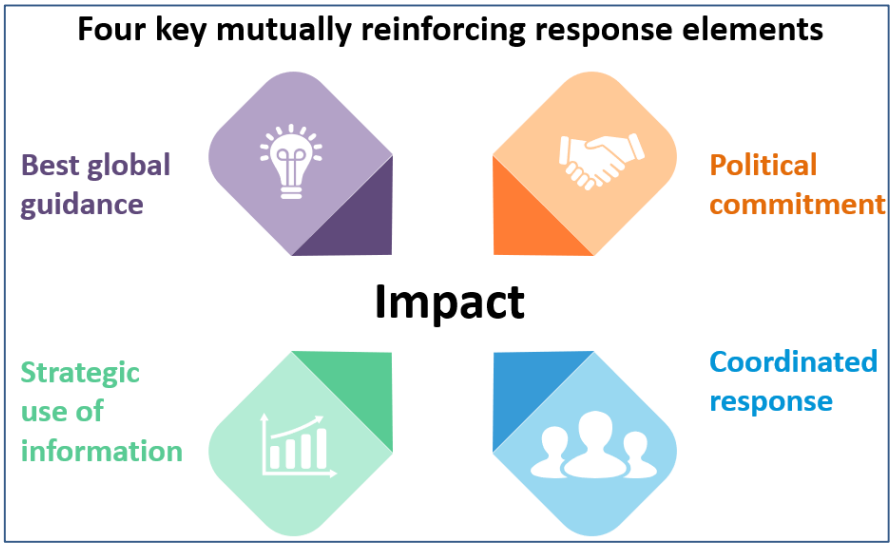


"What can we do with all the tools… to really make a difference in these countries?"

Dr Tedros

2 October 2019

Drug-based strategies to prevent malaria

- Chemoprophylaxis: e,g, in non-immune travellers or specific risk groups (e.g. children in endemic settings with sickle cell disease)
- Mass Drug Administration (MDA), the delivery of malaria treatment to every member of a defined population or geographic area at the same time
  - Accelerate progress towards interruption of transmission in pre-elimination settings
  - Ameliorate the worst effects of malaria in epidemics or complex emergencies
- Intermittent Preventive Treatments (IPT) e.g. infants (IPTi), women in pregnancy (IPTp), Seasonal Malaria Chemoprevention (SMC) for children 3-59 months
- Boundaries between chemoprophylaxis, MDA and the IPT's are blurred
  - Practical challenges of regular MDA results in something closer to mass IPT
  - High coverage of frequent MDA in some population subgroups may result in their chemoprophylaxis
- "Chemoprevention" - the general approach of using malaria drugs to prevent disease
  - Administration of treatment doses of anti-malarial drugs to specified groups, irrespective of signs or symptoms of disease, or the presence of *Plasmodium* infection

IPTi, SMC & IPTp

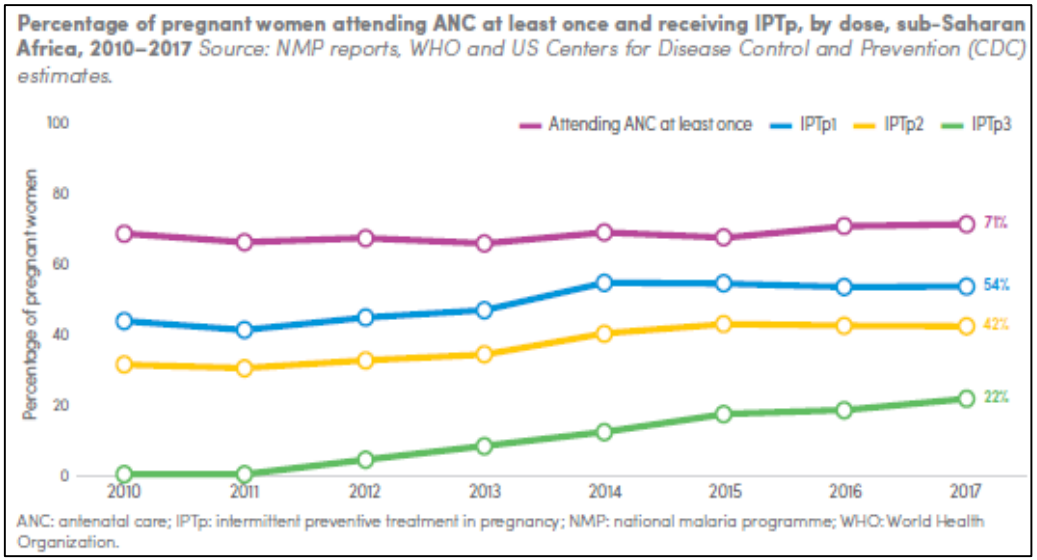
	To who	Where	How	When
IPTi (SP)	Infants	Areas of moderate to high malaria transmission in Africa	Through the routine vaccination schedule	All year around
SMC (AQ+SP)	Children aged 3–59 months	Highly seasonal malaria transmission areas in the Sahel sub-region in Africa	Mass delivery campaigns	During 4 months of high transmission
IPTp (SP)	Pregnant women	Areas of moderate to high malaria transmission in Africa	At each ANC visit from 2nd trimester, 1 month apart, at least 3 doses during pregnancy	All year around

(1) World Malaria Report 2018

Slide courtesy of Maria Tusell et al

Intermittent Preventive Treatments

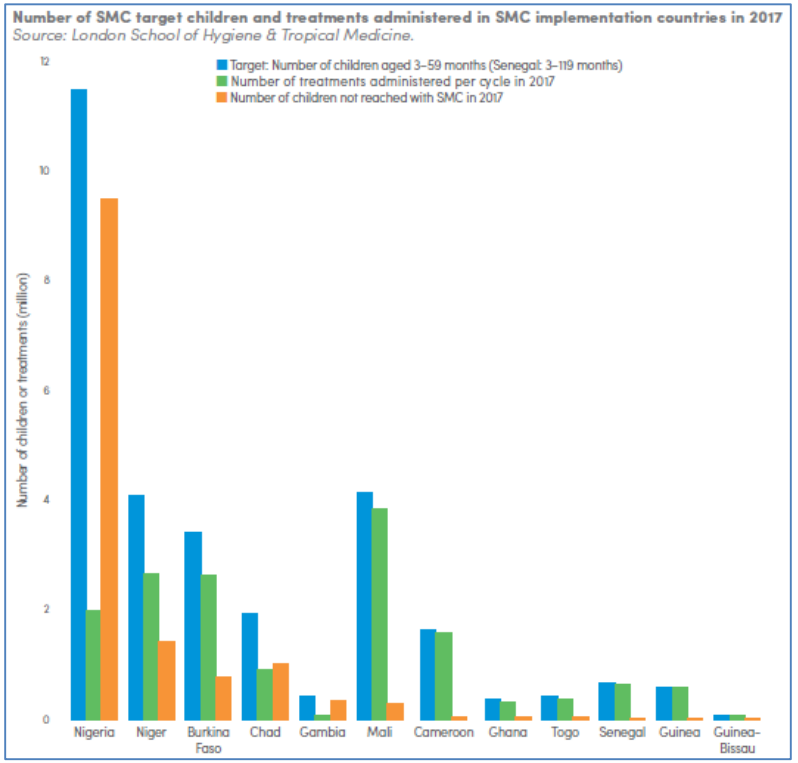
Implementation fragmented, strategies under-utilised



39 countries implementing IPTp

IPTi only adopted in Sierra Leone, in 2018

2016: 15 million children in 12 countries protected with SMC
(total eligible population ~25m)



World Malaria Report 2018

Policy process for chemoprevention strategies

IPTp timeline

1998

WHO Expert Committee on Malaria

"**Intermittent treatment** with an effective, preferably **one-dose antimalarial drug**, provided **as part of antenatal care**, should be made available…"

1994- 1999: Large scale trials in East Africa with IPTp-SP at the beginning of 2nd and 3rd trimesters

2004

A Strategic Framework for Malaria Prevention and Control During Pregnancy in the African Region

"should receive **at least 2 doses** of IPT after quickening"

2007

July 2007: TEG

"all countries in stable malaria transmission situations should **deploy and scale up** the strategy of SP-IPTp"

Ter Kuile et al, 2007: Systematic review on the effect of SP resistance on the efficacy of IPTp

2012

July 2012: ERG
September 2012: MPAC
October 2012: Updated WHO policy

IPTp with SP is recommended for all pregnant women at each scheduled antenatal care visit

Kayentao et al, meta-analysis of 7 trials which compared ≥3 vs 2 doses of IPTp-SP
MiP Consortium monitoring studies

2013

April 2013: WHO Policy brief
July 2013ERG
September 2013: MPAC

"should be considered by countries with specific patterns of **SP resistance**, or a **persistent reduction in malaria transmission** and by **those considering mefloquine…**"

Revision of the April 2013 WHO policy brief

WHO **urges** national health authorities to disseminate the recommendations from 2012 widely and ensure its correct application

Studies on the effectiveness of IPTp-SP in areas of resistance
Multicenter clinical trials that evaluate the efficacy and safety of mefloquine as IPTp

2016

WHO recommendations on antenatal care for a positive pregnancy experience

Antenatal care models with a **minimum of eight** contacts are recommended

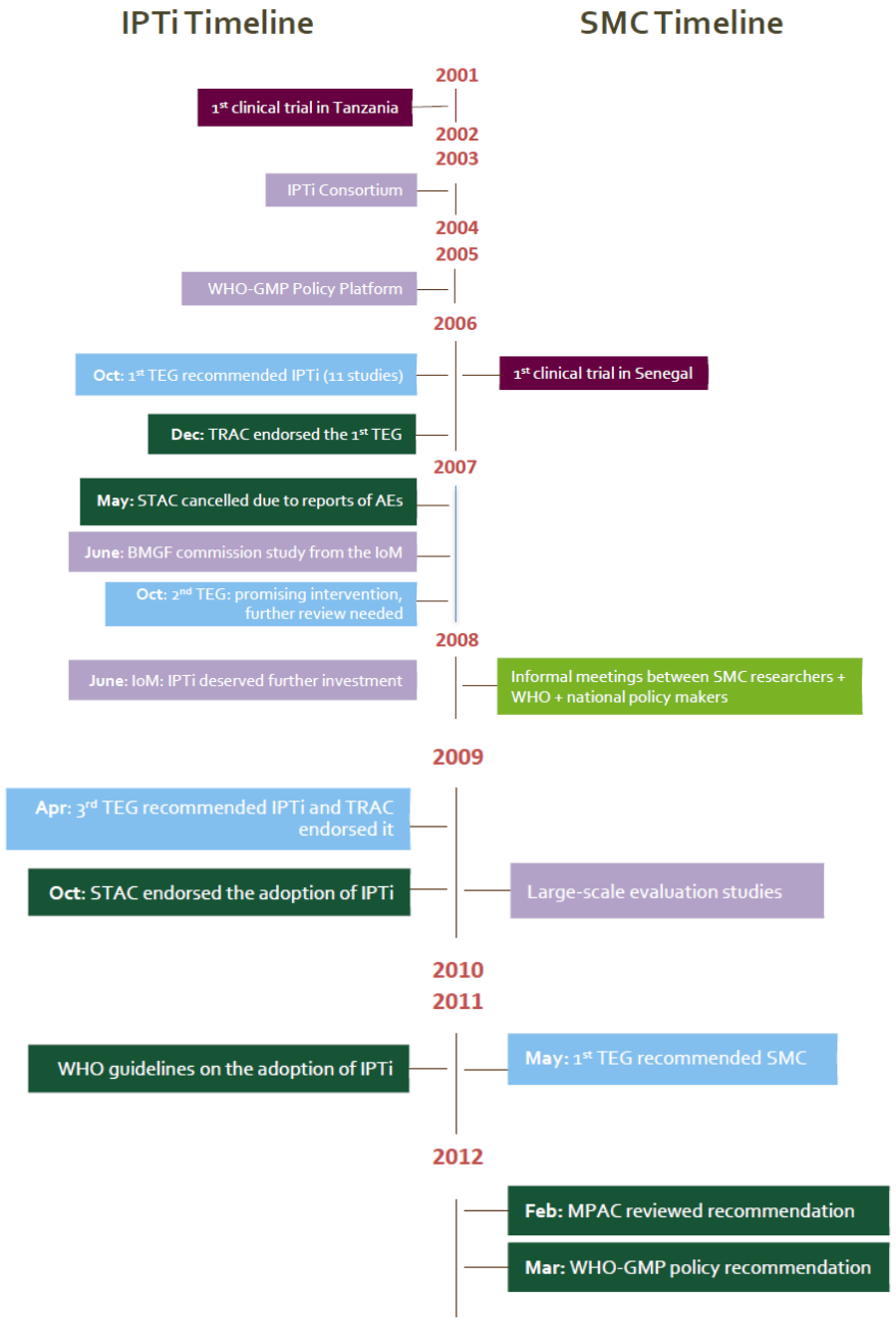
ISGlobal

Slide courtesy of Maria Tusell et al

MESA

Policy process for chemoprevention strategies

IPTi and SMC timelines



IoM: Institute of Medicine

Slide courtesy of Maria Tusell et al

Experience scaling up - SMC

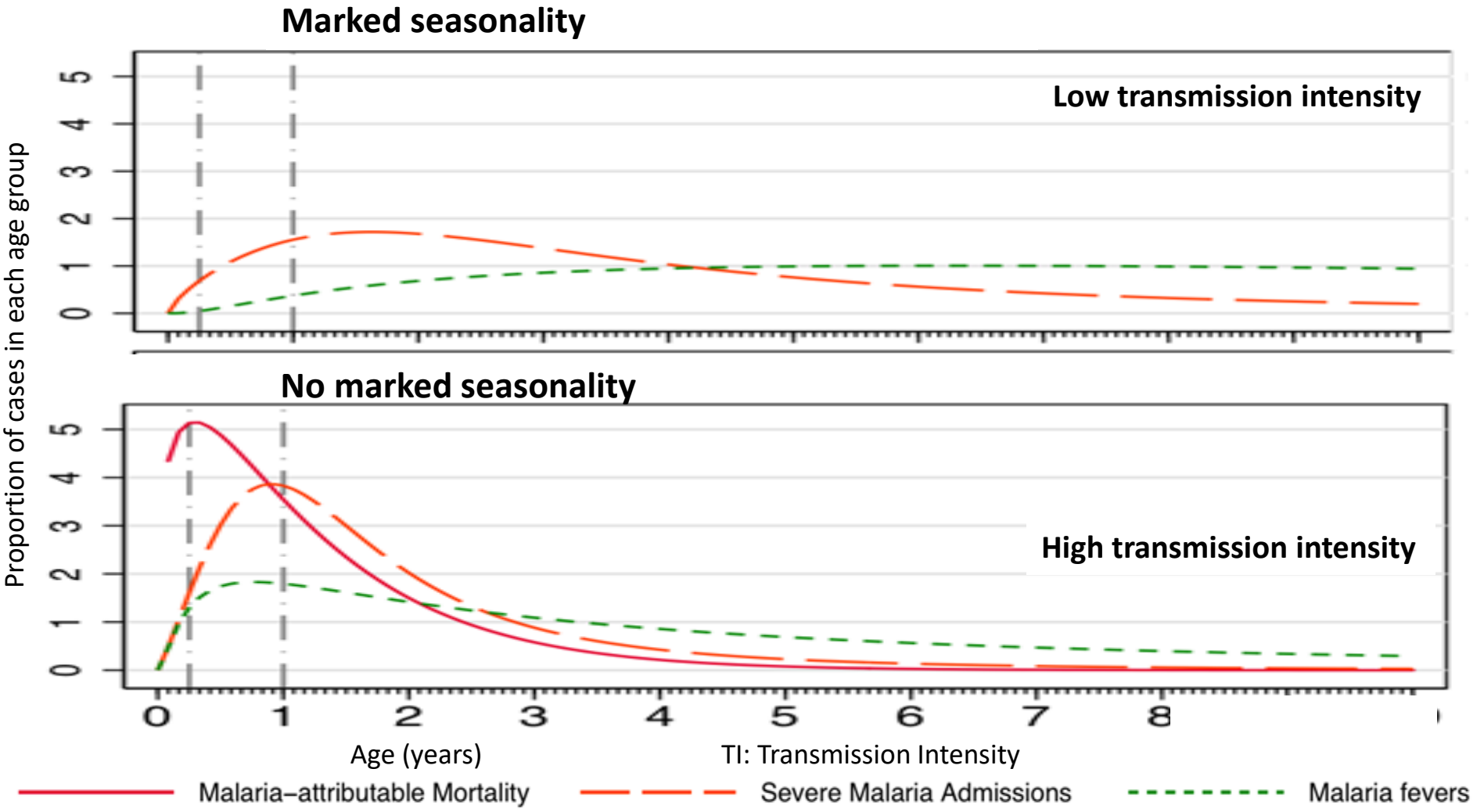
UNITAID investment to evaluate the effectiveness, operational feasibility (rainy season, often remote or nomadic Sahelian populations) and cost of delivering SMC at scale

Support for prequalification of a child-friendly dispersible formulation of SP-AQ

2016: 15 million children in 12 countries protected with SMC
(total eligible population ~25m)

Global **Malaria** Programme

Age patterns of infection, disease & death are different



Carneiro I et al. PLoS ONE 2010. 5(2): e8988. doi:10.1371/journal.pone.0008988

Enabling implementation of chemoprevention

1. **Implementation optimisation** - to reduce the incidence of disease, severe disease and death in currently eligible areas
   - UNITAID investments in SMC and IPTp are examples of targeted activities to catalyse improved use of chemoprevention in recommended settings
   - Additional investments may stimulate broader uptake of chemoprevention and help build demand for this highly cost effective family of strategies

2. **Review existing guidance** and constraints on the use of chemoprevention
   - E.g. chemoprevention & resistance

Research to guide the broader use of chemoprevention

- Implementation research: unlock the potential of existing strategies and drugs
  - Should geographic targeting / criteria for intensity of seasonality for SMC be relaxed?
  - Should the age groups targeted by IPTi and/or SMC be relaxed?
    - Improved malaria control increases the age group most affected by malaria
  - Can delivery of chemoprevention be enhanced through better integration with routine platforms?

- Other forms of chemoprevention
  - Post-discharge malaria chemoprevention
  - IPT in school children

- Can combined delivery of chemoprevention with other interventions (e.g. azithromycin) reduce all-cause mortality?

- What are the target product profiles for new drugs - and novel formulations - for malaria chemoprevention?

- Ensure availability of quality-assured drug supply

Planned discussions

Technical Consultation on Seasonal Malaria Prevention: Evidence for policy review

14 to 15 October 2019

Technical Consultation to Review the Role of Drugs in Malaria Prevention for People Living in Endemic Settings

- Based on existing policies for malaria chemoprevention and experience with their implementation, define strategies to maximise the impact of malaria medicines on mortality, morbidity and transmission.
- Define the evidence gaps and priority research needed to update WHO policies on malaria chemoprevention.

16 to 17 October 2019

Agenda overview

- Summary of the SMC consultation
- IPTp: Evolving evidence base, barriers & facilitators, changes in antenatal guidelines, delivery approaches
- IPTi: experience with implementation, why has uptake been limited?
- MDA: evolution of evidence base and policies, experience in emergencies & fragile situations
- IPT in school children, post discharge
- The drugs – resistance, product profiles

What is an ‘intervention’?

- MDA, SMC, IPTp, IPTi
  - All distribute antimalarial medicines to individuals at risk, without knowing their malaria infection status
  - All aim to clear any existing, and to prevent new, infections
  - Different target groups, drugs and delivery approaches

Are they different interventions or a range of strategies to deliver what is basically the same intervention?

Chemoprevention targets people at high risk of malaria

The improved use of chemoprevention has the potential to form an impactful component of the response to the ongoing high burden of malaria disease and death

Malaria Policy Advisory Committee Meeting
2–4 October 2019, Geneva, Switzerland
Background document for Session 6

Meeting report of the WHO technical consultation on malaria case management in the private sector in high-burden countries

1–3 May 2019, WHO Headquarters, Geneva, Switzerland

Summary

In February 2018, the World Health Organization (WHO) convened a Technical Consultation on "Universal access to core malaria interventions in high-burden countries" *(1).* It concluded that the private sector plays an important role in delivering malaria care in many high-burden countries, both in urban areas and in remote rural areas underserved by formal health care facilities.

In malaria-endemic countries, a large proportion of patients with fever first seek treatment through private health care providers, especially pharmacies, authorized and informal drug shops, and other medicine sellers. These providers are often collectively referred to as private medicine retailers (PMRs). The quality of case management in these facilities varies widely and is often poor, especially in terms of access to quality artemisinin-based combination therapies (ACTs) and malaria diagnostic testing prior to treatment.

There is limited evidence on the most effective methods to improve malaria case management in the PMR sector. Under the Affordable Medicines Facility–malaria (AMFm) pilot (2010–2013), medicine subsidies improved both the availability and affordability of treatment, especially when combined with a significant behaviour change communication (BCC) programme promoting the use of quality ACTs for malaria treatment. AMFm was transitioned into the Global Fund's Private Sector Co-Payment Mechanism (CPM), but countries have been terminating or decreasing their investments in ACT subsidies for the private sector because of competing health priorities. With the demise of the CPM, there is a risk of reduced affordability and availability of quality ACTs in the private sector.

During the Technical Consultation, country representatives were concerned that the requirement by international funding agencies for medicines and diagnostics to be approved by a stringent regulatory authority (SRA) or prequalified by WHO was reducing competition for quality ACTs in the antimalarial market and thus reducing access. The representatives felt that there were products whose quality was assured by the national registration process, but because they were not WHO-prequalified, such products were denied for procurement with international funds. Furthermore, country representatives felt that the term "quality-assured ACT (QAACT)" should not be equated with SRA approval or WHO prequalification, as there are quality-assured products that are only approved by national regulatory authorities (NRAs). At the same time, it was noted that NRAs frequently lack the resources required to review and update regulatory requirements or enforce regulations. There was general consensus that pricing needs to reflect manufacturing quality requirements in order to ensure a sustainable supply of high-quality drugs and malaria rapid diagnostic tests (mRDTs) in the medium to long term.

WHO/CDS/GMP/MPAC/2019.12

The AMFm did not include malaria diagnostic testing. As a result, a considerable number of febrile patients without malaria were given ACTs and many with malaria were not. Evidence on how to increase testing with mRDTs in the private sector is limited. Testing in the private sector is hampered by policies and regulations that restrict where mRDTs can be sold and performed, as well as by the lack of clear protocols for managing non-malarial febrile illnesses, and the lack of financial and non-financial incentives to support malaria testing prior to treatment. Studies have shown that non-medical staff in a variety of private health care settings can administer an RDT and adhere to the test result (often better than doctors and nurses), provided they have been well trained and receive follow-up supervision. Evidence from other disease programs also supports the need for strong BCC programmes in order to change the health care expectations and behaviour of the general public, which have a major influence on the behaviour of providers in the private sector.

PMRs could also be a valuable source of data for national surveillance systems, particularly where they are a common source of care; however, there is very little experience in including these providers in national health management information systems.

The integration of PMRs into national efforts to reduce the burden of malaria was seen to be an important area of intervention, paving the way for the sector's wider involvement in supporting countries to achieve universal health coverage (UHC).

Based on the high proportion of patients accessing care for febrile illness in the formal and informal private sectors in Chad, Democratic Republic of the Congo (DRC), Kenya, Ghana, Niger, Nigeria, United Republic of Tanzania and Uganda, participants were asked to identify the main bottlenecks in accessing quality malaria case management in the private sector in their country and to prioritize steps to reduce barriers, promote best practice and increase access. Each country situation is unique, but certain common themes were identified, as presented below.

Common vision

- All patients, irrespective of their social status or where they live, have the right to access quality malaria case management.
- As many patients seek treatment for febrile illness first through the private sector, this sector must be able to deliver quality malaria case management.
- Private sector health care providers need to be considered an integral part of a country's national health system.

Key themes

- **Promotion:** Governments, national malaria control programmes (NMCPs) and other key stakeholders need to generate demand among the population for better quality care in the private health sector. BCC activities targeting the general public need to continue to promote malaria diagnostic testing and compliance with the results.
- **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector can be enhanced through:
    - accreditation systems for drug shops;
    - training in malarial and non-malarial fever case management and professional development schemes for private health care providers;
    - supervision of private health care providers, ideally by existing government health care workers;
    - increasing the availability and affordability of quality diagnostics and medicines.

- **Policy and regulation:** Country policies and regulations should be reviewed and revised to support and promote the implementation of appropriate case management in the private sector.
    - There should be clarity and consistency of policies and regulations on where mRDTs can be sold and who can perform them, and where antimalarials can be accessed and who can prescribe and/or sell them, taking into account client care-seeking practices.
    - Policy makers and regulators should be aligned on the technical specifications required for health products (diagnostics and medicines).
    - Policies and regulations should support the extension of quality malaria testing to ensure the rational use of malaria medicines.
    - Guidance should be developed and behaviour change promoted to ensure that health care providers and patients know what should happen in the event of a negative malaria test result.
    - There should be robust supervision and enforcement of existing and new regulations, supported by training and follow-up programmes.
- **Market information:** The lack of detailed current information on private sector antimalarial and RDT market dynamics, especially outside the large urban areas, should be addressed and results should be disseminated among all stakeholders. As countries differ, each needs to undertake an in-depth market review, with periodic updates to monitor progress and inform future actions.
- **Surveillance:** Simple systems should be developed to allow the private sector to be fully integrated into national malaria surveillance systems, and providers should be supported to report complete, accurate and timely data through training, supervision and appropriate incentives.
- **Pricing and incentives:** Countries should ensure that:
    - quality-assured products crowd out poor-quality and inappropriate products through pricing and other measures that make them preferred by patients and providers;
    - the cost to the caregiver/patient of the testing and treatment package is affordable and promotes appropriate case management;
    - tax and tariff systems for finished products are aligned so that diagnostics are not disadvantaged compared to quality ACTs or other pharmaceutical products.
- **Coordination:** Different stakeholders are not always aligned on how to involve the private sector in delivering quality case management. It will be necessary to bring all groups together so as to work out ways to overcome this constraint, under the stewardship of government.

The meeting also identified areas where the participants would like to see support and guidance from WHO.

Key requests to WHO

- **Advocacy:** Advocate for the importance of the private sector in order to ensure that quality case management is available to all, as an essential component of achieving UHC.
- **Support and guidance**: Provide support to governments (including sharing best practice) on how best to engage the private sector in terms of:
    - facilitating cross-sectoral coordination through country-based forums;
    - making investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.
- **Quality case management:**
    - Provide guidance on how to assess the quality of care in the private sector, not just the quality of health products.
    - Ensure continued promotion of appropriate use of malaria diagnostics in order to deliver quality care for febrile illnesses in malaria-endemic countries.
    - Make recommendations on the correct protocols to follow in the event of a negative mRDT, acknowledging the actual pressures on the ground.
- **Affordability:** Based on a range of business models/pricing strategies, make recommendations on how quality case management can be made affordable to patients, while ensuring a reasonable return to private health care providers.
- **Innovation:** Develop innovative systems and incentives to promote best practice for case management and reporting from the private sector and to integrate the sector into national surveillance systems.
- **Local manufacturing:** Support technology transfer in malaria-endemic countries in order to increase local production of ACTs and mRDTs that meet the quality requirements needed for procurement with international funds.

Ideally, this guidance should be brought together into a **Roadmap** (similar to the TB Roadmap) for integrating the private health care sector into national strategies to improve malaria case management. This guidance should provide direction to ministries of health and other national agencies on how best to engage the private sector, especially PMRs, to deliver quality diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.

List of abbreviations

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
AL	artemether-lumefantrine
AMFm	Affordable Medicines Facility–malaria
BCC	behaviour change communication
CHAI	Clinton Health Access Initiative
CHW	community health worker
CIP	coalition of interested parties
CPM	Co-Payment Mechanism
DHIS	District Health Information System
DHS	Demographic & Health Survey
DRC	Democratic Republic of the Congo
FLB	first-line buyer
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Global Malaria Programme
HMIS	health management information system
HoG	head of government
IMCI	Integrated Management of Childhood Illness
IVD	in-vitro diagnostics
MIS	Malaria Indicator Survey
MPAC	Malaria Policy Advisory Committee
mRDT	malaria rapid diagnostic test
NMCP	national malaria control programme
NRA	national regulatory authority
ORS	oral rehydration salts
OTC	over-the-counter
OTCMS	over-the-counter medicine seller
PMR	private medicine retailer
POM	prescription-only medicine
PPMV	patent and proprietary medicine vendor
QAACT	quality-assured artemisinin-based combination therapy
SRA	stringent regulatory authority
SSA	sub-Saharan Africa
TB	tuberculosis
UHC	universal health coverage
WHO	World Health Organization
WHO-PQ	WHO Prequalification

Background

In February 2018, the World Health Organization (WHO) convened a Technical Consultation on "Universal access to core malaria interventions in high-burden countries" *(1)*. The Technical Consultation responded to the upward trend in the number of malaria cases in 2016 and 2017, which reversed a decade of downward trend. The meeting's findings and conclusions were reported to the Malaria Policy Advisory Committee (MPAC) at its April 2018 meeting *(1)*.

One conclusion of the February 2018 meeting was the importance of the private health sector, especially private medicine retailers (PMRs)[1], for delivering malaria case management. PMRs are often the part of the health care system in closest proximity to the patient, located in their village or urban suburb. This is especially true in areas that are underserved by the general government-run health and community services. Therefore, PMRs are often the first place that many patients and caregivers go to seek treatment for febrile illness. However, the specific needs and differences of private health services are not usually addressed in national strategies and plans for delivering appropriate and quality care close to the patient. The principal challenges to the uptake of national strategic plans and policies among PMRs are:

- the poorly regulated, unsupervised nature of the private sector, which leads to non-conformity with national policies and guidelines, as well as:
    - overall poorer quality of available products and quality of care
    - low use of diagnostics for malaria in retail treatment outlets;
- no clear guidance or policies to support collaboration between the public sector and PMR outlets.

A key challenge in improving access to appropriate diagnosis and treatment through PMRs is ensuring that quality products are available and affordable, and can compete with poor-quality products. Co-payments for quality artemisinin-based combination therapies (ACTs) have often been used, for example, in the Affordable Medicines Facility–malaria (AMFm) and more recently in the Global Fund's Co-Payment Mechanism (CPM). However, the lack of dedicated funds and competing priorities for malaria funding have caused national malaria control programmes (NMCPs) to deprioritize this type of approach.

The meeting concluded that, in order to expand access to quality care for malaria patients, it is important for the private health sector to be seen as a valid and essential health delivery platform that complements the public health sector. However, many government and public-sector agencies have little experience of working with the private sector and need guidance and advice on how to properly engage with private providers.

Objectives of the Technical Consultation

1. Review the data supporting the rationale for an international effort to engage private sector players in malaria case management and the evidence base that this can be done safely and effectively.
2. Review the laws, regulations and policies influencing the use of medicines and point-of-care diagnostic tests in malaria case management in a set of high-burden countries in Africa.

[1] Private medical retailers are defined as pharmacies, authorized drug shops and outlets in the informal private sector (shops, markets, kiosks, itinerant drug vendors, etc.).

3. Based on this review, identify the main bottlenecks and outline steps, including research priorities, to reduce barriers and thus enable improved quality of care for malaria across the entire health sector.
4. Draw upon documented lessons learned from major global, regional and country initiatives to improve malaria case management in the private sector, including the Global Fund CPM, the Unitaid project *Creating a private-sector market for quality-assured RDTs*, Population Services International's (PSI) *A roadmap for optimizing private sector malaria rapid diagnostic testing,* the accredited drug dispensing outlet (ADDO) project in the United Republic of Tanzania, and the Global Fund's framework for engaging the private sector in malaria case management.
5. Review the results of recent private sector outlet surveys, and the main determinants of supply chain and distribution mechanisms for malaria medicines and diagnostics in the private sector, taking into account the experience of pharmaceutical and diagnostic companies in priming the market in high-burden malaria-endemic countries.
6. Identify key lessons learned and best practices from other public health programmes, including childhood diarrhoea and tuberculosis (TB), with a long history of private sector stakeholder engagement.

Process

The meeting was attended by representatives of the five countries in sub-Saharan Africa (SSA) where, according to countrywide household surveys conducted in 2014–2017, the majority of febrile children (under 5 years) seek treatment in the private sector: Chad, Democratic Republic of the Congo (DRC), Ghana, Nigeria and Uganda. Two other African countries were added to the list of selected countries – the United Republic of Tanzania and Kenya – due to multiple initiatives that have been undertaken in the private sector in recent years.

In preparation for the meeting, the WHO Global Malaria Programme (GMP) asked the collaboration of Clinton Health Access Initiative (CHAI), the Malaria Consortium and PSI to prepare profiles of each of the seven countries with respect to their policies, regulations and practices in the use of antimalarial medicines, antibiotics and in-vitro diagnostics (IVDs) through both desk reviews and interviews with selected officials at the ministries of health, national regulatory authorities (NRAs) and other relevant bodies. The individual country reports, a multi-country comparative analysis of findings, and selected published materials were circulated in advance of the meeting to participants *(2)* (see Annex 1). Most of the sessions began with a short summary presentation of the evidence based on the relevant pre-reads, followed by a discussion involving all participants. CHAI and PSI presented on their survey of first-line buyers (FLBs) involved in sustained procurement of medicines as part of the Global Fund CPM in Ghana, Kenya, Nigeria, Tanzania and Uganda. Several manufacturers of WHO-prequalified ACTs and rapid diagnostic tests (RDTs), who supplied products to the seven countries represented at the meeting, were invited and contributed their views through a dedicated panel session for manufacturers (see list of participants in Annex 2).

In the second part of the meeting, participants were assigned to breakout groups by country in order to discuss the role of the private sector in delivering high-quality malaria case management in each country (see agenda of the meeting in Annex 3). Using a methodology adapted from PSI's "Keystone Design Framework"[2], they identified the main bottlenecks/market constraints along the antimalarial and RDT supply chains that hinder the provision of high-quality private sector case management.

[2] See https://www.psi.org/2018/11/the-key-to-effective-health-solutions/

They next discussed how to prioritize steps to reduce these barriers and promote best practice in order to improve sustainable access to quality care for malaria in the private sector (see Annex 4 for Framework templates). The aim was not to define a comprehensive, prioritized list of actions in each country, but rather to stimulate thinking and identify common constraints across countries that need to be addressed and could inform a global roadmap for improving access to malaria case management in high-burden countries.

The report of the meeting was prepared by Ian Boulton and shared with all participants for comment; their inputs were taken into consideration in finalizing the report.

Private sector involvement in malaria case management

Current situation

The private health care sector is a major provider of diagnosis and treatment of malarial and non-malarial fevers in many malaria-endemic countries. The private sector is typically considered to include any facility, outlet or individual that provides health services, but is not managed by the government. The private sector is very diverse, ranging from private for-profit and not-for-profit health facilities and laboratories, to pharmacies and drug stores, to general stores, street vendors and traditional practitioners. In some settings, care providers may be highly trained and qualified, with access to state-of-the-art diagnostic and treatment options, while in other settings, providers may have no formal training or qualifications. Data from nationally representative Demographic and Health Surveys (DHS), Malaria Indicator Surveys (MIS), and ACTwatch surveys in 2014–2017 were reviewed for the Technical Consultation.

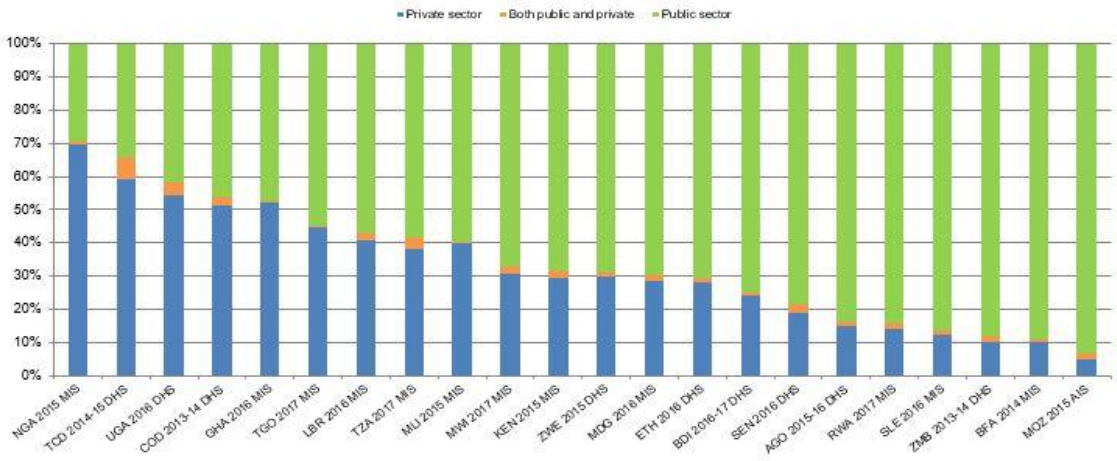
For the purpose of the analysis, the private sector was classified into three groups: i) formal medical private health facilities (hospitals, clinics, doctors, nurses, etc.); ii) pharmacies and authorized drug shops, and iii) informal private sector (shops, markets, kiosks, itinerant drug vendors, etc.).

Based on 19 nationally representative surveys conducted between 2015 and 2017 in SSA, initial treatment-seeking behaviour for a febrile child was *(3)*:

- no treatment sought (median: 40%)
- treatment sought in the public sector, including community health workers (CHWs) (median: 39%)
- treatment sought in the formal and informal private sector (median: 15%).

However, the results on where treatment was sought for febrile children varied widely between countries (Fig. 1). In Chad, DRC, Ghana, Nigeria and Uganda, caregivers of febrile children sought initial treatment in the private sector in more than 50% of cases.

Fig. 1. Where treatment is initially sought for febrile children



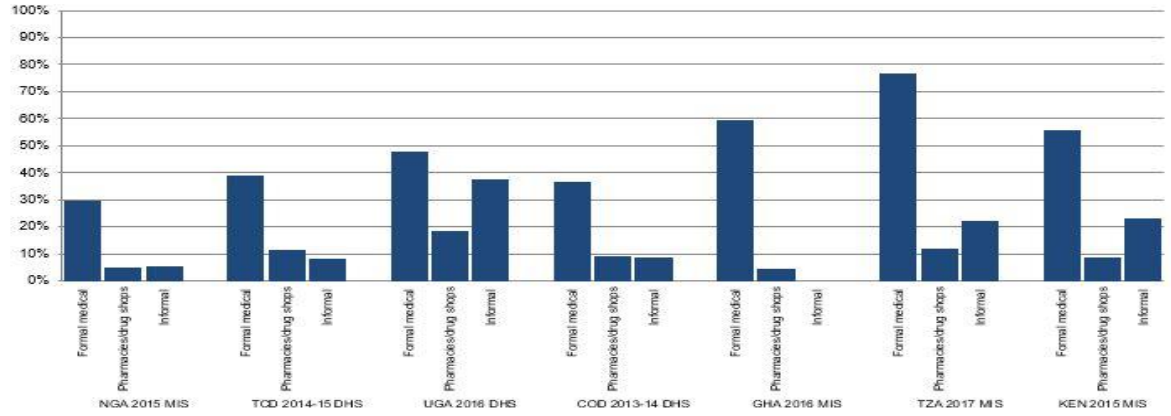
Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Country codes: AGO: Angola; BDI: Burundi; BFA: Burkina Faso; COD: Democratic Republic of Congo; ETH: Ethiopia; GHA: Ghana; KEN: Kenya; LBR: Liberia; MDG: Madagascar; MLI: Mali; MOZ: Mozambique; MWI: Malawi; NGA: Nigeria; RWA: Rwanda; SEN: Senegal; SLE: Sierra Leone; TCD: Chad; TGO: Togo; TZA: United Republic of Tanzania; UGA: Uganda; ZMB: Zambia; ZWE: Zimbabwe.

The split between formal private sector, pharmacies/drug stores and informal private sector also varied significantly between countries. This difference is driven by a range of factors, which underlines the need for each country to conduct a situation analysis in order to fully understand its particular private sector situation. Only then should plans be developed to incorporate the private sector into the delivery of malaria case management.

The quality of case management, especially malaria testing prior to treatment with antimalarials and/or other medicines, also varied and needs to be better understood. About 50% of febrile children had a blood test administered prior to treatment. However, among children seeking care in pharmacies and the informal sector, this percentage was only about 10–11% compared to 50–60% for those seeking care in the public sector and formal private medical health facilities.

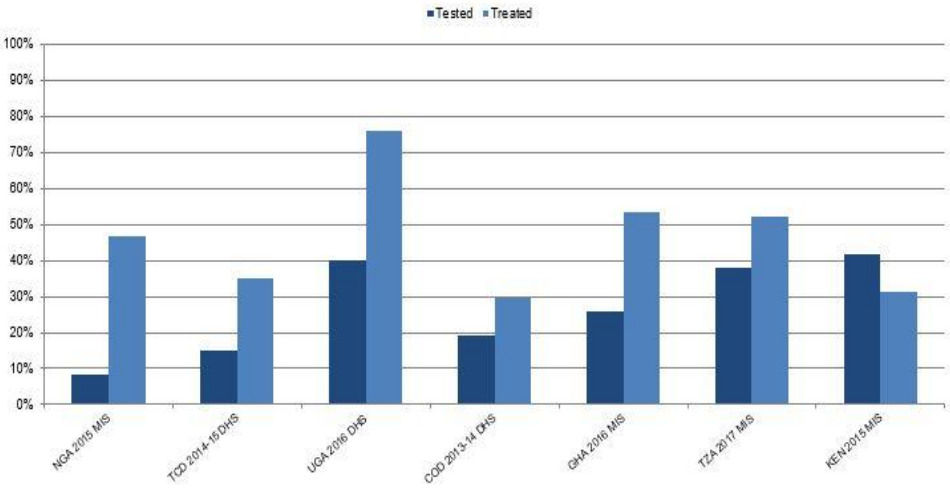
Focusing on the countries represented at the meeting, there were also great differences (Fig. 2). Formal medical facilities were more likely to administer a blood test prior to initiating treatment, but this varied widely between countries (30–77%).

Fig. 2. Diagnostic testing in the private sector



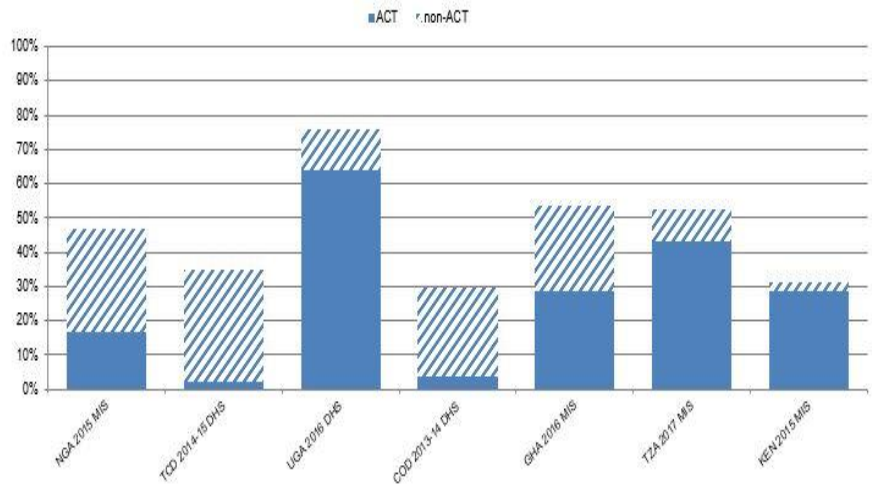
Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Country codes: AGO: Angola; BDI: Burundi; BFA: Burkina Faso; COD: Democratic Republic of Congo; ETH: Ethiopia; GHA: Ghana; KEN: Kenya; LBR: Liberia; MDG: Madagascar; MLI: Mali; MOZ: Mozambique; MWI: Malawi; NGA: Nigeria; RWA: Rwanda; SEN: Senegal; SLE: Sierra Leone; TCD: Chad; TGO: Togo; TZA: United Republic of Tanzania; UGA: Uganda; ZMB: Zambia; ZWE: Zimbabwe.

Fig. 3. Children tested and treated



Regrettably, across all types of private facilities, the proportion of febrile children treated was higher than those who received a blood test, with the only exception being Kenya (Fig. 3). Furthermore, the percentage of febrile children under 5 who received a diagnostic test did not exceed 40% in any of the seven countries.

Fig. 4. Antimalarial usage among children in the private sector



There were also some significant differences between the seven countries in terms of the types of antimalarials being prescribed to febrile children in the private sector (Fig. 4).

In Kenya, United Republic of Tanzania and Uganda, there was an encouraging level of ACT usage in the private sector.

In urban areas, use of the private sector is generally higher among people with higher income and education levels, but in rural areas, the private sector is the primary source of care for a significant proportion of people who are among the poorest and have low education levels.

These results do come with some important qualifiers:

- There are potential biases due to the timing of the surveys and the seasonality of malaria in the respective countries.
- Information on the treatment-seeking behaviour of under-5s is not representative of the population as a whole, as it differs for older children and adults.
- The results are based on surveys and so will be affected by the concept of fever, which differs between countries and populations.
- There is also a problem of recall bias or mistakes in reporting the medicines by the caregiver.

Key Conclusions

- The private sector, especially PMRs, represents an important source of care for febrile patients in SSA. The malaria care provided by different private health care providers varies in the formal medical facilities, pharmacies and authorized drug shops, and the informal sector. It also varies considerably between countries, driven often by ease of access and affordability.
- Diagnostic testing before treatment for fever in PMRs remains at a low level (about 10% across the seven participant countries).

Current evidence base to support improving private sector case management

Given the importance of the private sector in delivering malaria case management to febrile patients, it is important to understand the factors and levers that will improve this delivery. The Global Fund technical brief for malaria case management in the private sector *(4)* considers that engaging with the private sector has the following objectives:

1. *Product quality:* Ensure that only quality antimalarial medicines and diagnostic testing are available from private providers.
2. *Availability and affordability:* Increase the availability and affordability of quality-assured antimalarials and diagnostic services.
3. *Quality of care:* Improve case management by private providers.
4. *Consumer knowledge:* Increase consumer knowledge and awareness of appropriate treatment seeking, diagnosis, medicine choice and adherence.
5. *Surveillance:* Improve malaria surveillance in the private sector.

There is some evidence on effective approaches and best practices to achieve these objectives.

Product quality: This is achieved through proper regulation and its enforcement by the national and state regulatory authorities. However, as is well established, many countries have insufficient resources to achieve this objective, even if the regulations themselves are adequate. Regulatory and screening efforts have had a positive effect in reducing the market share of oral artemisinin monotherapies. Mechanisms to assess quality and information on multiple suppliers of quality ACTs and RDTs are available, and the procurement of quality medicines and diagnostics is supported by international donor funds.

Availability and affordability: The most extensive study on increasing the availability of quality-assured antimalarials was the AMFm, which ran in seven countries in SSA between 2010 and 2013 *(5)*.

The AMFm was fundamentally a mechanism designed to crowd out non-ACTs and substandard drugs. It had three elements to increase the availability and affordability of ACTs in the private sector:

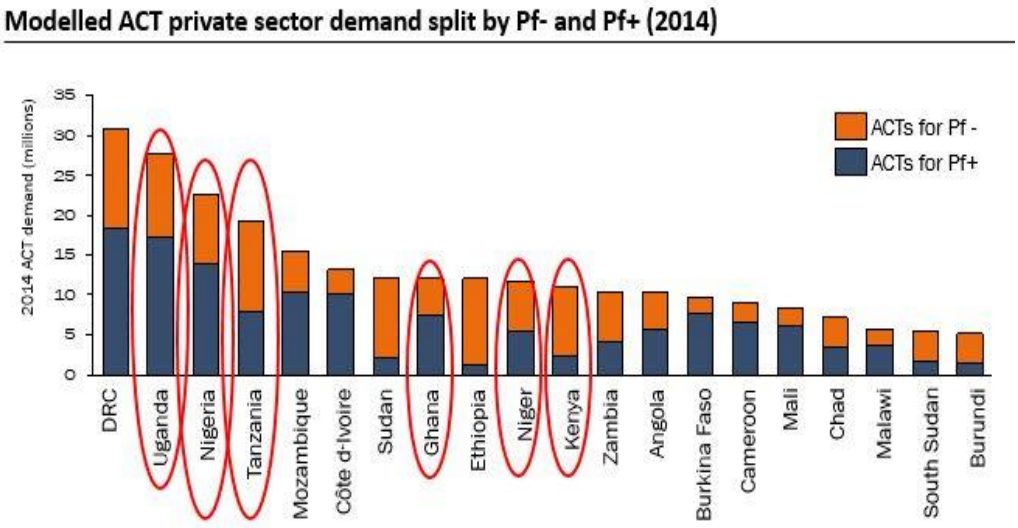
- negotiated lower prices from manufacturers for quality-assured ACTs (QAACTs)[3]

[3] In the AMFm, QAACTs were defined as ACT products that had been approved by a stringent regulatory authority (SRA) or prequalified through the WHO Prequalification (WHO-PQ) procedure.

- manufacturer-level subsidies to reduce the price-to-consumer to an affordable level similar to other antimalarials
- extensive behaviour change communication (BCC) activities in the general public to promote the use of QAACTs over other antimalarial treatments (including non-QAACTs).

It was shown that the AMFm approach could achieve great reductions in the median price-to-consumer, and large increases in QAACT availability and the market share of antimalarials sold. Following the pilot, the approach was incorporated into the regular Global Fund grant system as the CPM. However, countries have found it difficult to allocate funding to the CPM. Without a dedicated funding stream as in the AMFm, the CPM is part of the same grant funding and thus competes with other priorities.

Fig. 5. High levels of inappropriate use of QAACTs



A problem with the AMFm approach was that it did not directly incorporate malaria testing prior to treatment. Consequently, there was significant consumption of QAACTs for non-malarial fevers, wasting valuable resources and increasing the risk of resistance development (see Fig. 5[4]) *(6)*. In addition, many PMR patients with malaria failed to obtain QAACTs. While drug availability and affordability are necessary conditions, they are not sufficient to ensure appropriate use and quality malaria case management.

Unitaid's Private Sector RDT Project attempted to investigate ways to improve the availability of RDTs. Visser et al. *(7)* reviewed this project, along with other studies targeting PMRs. The results of the review showed that the level of RDT uptake in the private retail sector ranged from 100% to below 15%. Subsidies were used in most of the implementation projects. Price to patient/caregiver varied across the studies – between US$ 0.00 and US$ 1.50. Broadly, the lower the cost to patient, the higher the level of uptake; but the length of training and frequency of follow-up also had an influence (see below).[5]

[4] Countries that participated in the AMFm are ringed. Methodology was taken from Cohen et al. *(6)*, and the model has been updated using 2014 data.

[5] Recently, Prudhomme et al. *(8)* published a study on the use of vouchers to promote testing before treatment for patients with fever. Results showed that this approach could have a positive impact on the uptake of pre-testing.

A major challenge in operationalizing the Unitaid project was that countries would not permit staff in many types of private sector outlets (e.g., pharmacies and accredited drug shops) to perform malaria RDTs (mRDTs) and so waivers were needed before the project could be implemented. Continued efforts during the project's lifespan resulted in regulatory changes in Nigeria, Uganda and Madagascar that allow for long-term continued use of rapid diagnostic testing services in PMRs. However, in Kenya, PMRs could not continue to administer the tests legally after the end of the project.

The uptake of RDTs in the private retail sector varies widely. Moreover, the market for diagnostics in the private sector is hampered by consumer expectations and demand for medicines, low profits, and no clear protocols for managing a negative mRDT result.

Quality of care: To deliver quality case management in PMRs, providers must be supported by training, supervision and protocols that are appropriate to the characteristics of the delivery channel and the providers. The Unitaid Private Sector RDT Project also tested a range of approaches to strengthen case management quality and concluded that:

- The introduction of schemes to improve case management must be accompanied by adequate training for staff, which needs to be followed-up and reinforced on a regular basis. Training that lasted four to five days and was followed up weekly for one to two months showed significantly better results than shorter training periods with less frequent follow-up. Adequate training and follow-up address the principal issues related to staff turnover and staff members' lack of confidence when dealing with caregivers.
- Lay workers in PMRs can administer mRDTs successfully and adhere to test results, often better than health professionals in formal medical health facilities. This finding was also related to the length of training and follow-up, as well as emphasis on adherence in the training.
- There is a need for therapeutic alternatives in the event of a negative test result in order to avoid frustration on the part of both the PMR staff and the caregivers.
- Caregivers may ignore the advice of the PMR staff and simply go to another shop where they may be able to obtain some medicines, even if they are inappropriate.

There is a need for a more holistic approach to engaging with the private sector on diagnosis – one that includes management of non-malarial febrile illnesses. However, more guidance is needed, especially for resource-poor settings.

Consumer knowledge: The AMFm Independent Evaluation documented the extent of the supporting interventions involving communications with the general public about malaria case management (although these did not cover the need for prior diagnosis). In the AMFm areas, communication campaigns that lasted longer showed the greatest increase in the market share of QAACTs delivered by the programme.

Many programmes to introduce ACTs and RDTs in the private sector have included BCC activities, but there is limited evidence on the effectiveness of the different approaches implemented in private sector settings.

Surveillance: The third pillar of the WHO Global Technical Strategy for malaria *(9)* is to transform surveillance into a core intervention. Currently, there is very limited reporting on malaria case management in the private sector, especially from PMRs. Even where PMRs are able to perform malaria tests, reporting into the health management information system (HMIS) has yet to be fully implemented. There is little evidence on how best to enable and encourage PMR providers to report data as part of the national surveillance system. In Uganda, PMRs in three districts were trained and equipped to report to the national HMIS system – and this was made mandatory. In the United Republic of Tanzania, ADDOs were also equipped and trained to report into the District Health

Information System (DHIS2), but this was not made mandatory. Over the three months in 2018 immediately after its introduction, reporting rates from the ADDOs fell from 69% to 53%. Frequent follow-up and an easy reporting system seem to be keys to successfully integrating PMRs into national surveillance systems.

Potential approaches to achieve the objectives: Montagu and Goodman *(10)* proposed that it is possible to classify strategies for improving private sector performance into four approaches: prohibit, constrain, encourage and purchase (see Fig. 6).

Improving clinical quality is challenging and requires strong incentives. Working with the formal private sector will only reach the poor if a significant financing component is included. The use of demand-side financing (such as voucher schemes) can facilitate scale-up of services in the private sector but requires strong governmental capacity to manage this successfully. It is therefore important to also consider links with other financing mechanisms such as social health insurance.

Fig. 6. Approaches and devices for private sector engagement

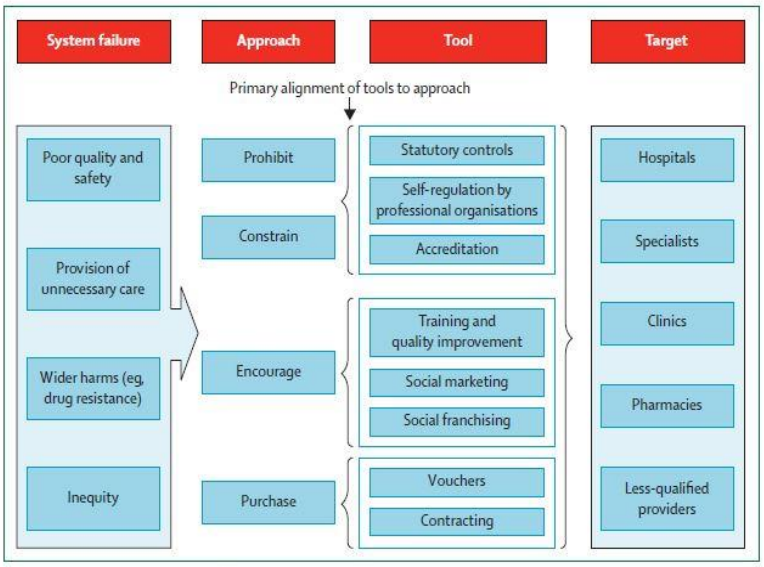


Figure: Approaches and devices for private sector engagement

Source: Montagu D, Goodman C. Prohibit, constrain, encourage, or purchase: how should we engage with the private health-care sector? Lancet. 2016;388:613–21.

Guidance and recommendations on approaches for better engagement with the private sector in delivering quality malaria case management have been published by the Global Fund *(4)* and PSI *(11)*.

Key Conclusions

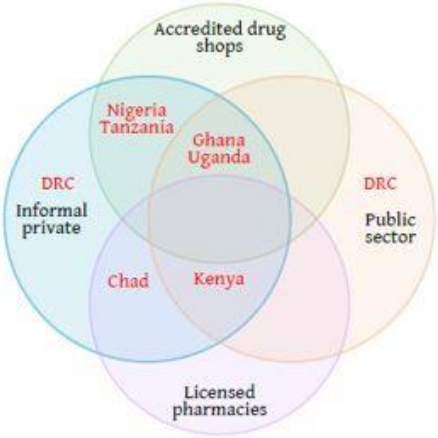
- There is a limited amount of evidence to support the different ways to improve case management in PMRs.
- If research and pilot projects are ever to move to scale, regulatory restrictions on who can test, treat and sell health products need to be removed so that tasks can shift to where patients are accessing care.
- **Availability and affordability:**
    - Lowering the purchase costs (through co-payments or subsidies) of quality-assured antimalarials and diagnostic services or providing quality-assured commodities free of charge to providers and patients (together with associated BCC programmes) can increase availability and affordability.
    - However, in the absence of pre-treatment diagnostic testing, increased availability and affordability of ACTs may lead to a high level of inappropriate treatment of non-malarial fevers.
- **Quality of care:**
    - There is less evidence on the best way to introduce mRDT testing into PMRs. The Unitaid project and other studies have shown that PMR staff can successfully administer tests and adhere to the results, often better than formal health care workers. However, as in the public sector, there needs to be adequate training and regular follow-up.
    - Appropriate protocols for the management of non-malarial fevers are also required.
        - Patients testing negative for malaria may go elsewhere to get treatment.
        - PMRs may feel legitimized to diagnose and treat other diseases without proper guidance.
    - Thus, a more holistic approach is required – one that goes beyond malaria to include other aspects relevant to real-life settings where resources are limited.
- **Consumer knowledge:**
    - BCC is crucial to changing consumer behaviours and expectations when seeking care in PMRs.
    - Demand for testing services does not exist everywhere and testing is often not perceived as a service that has to be paid for.
- **Surveillance:**
    - There is little experience on developing appropriate surveillance for the private sector, with appropriate tools, incentives and systems.

Regulation and enforcement

The analysis of policies and regulations that affect malaria case management in the private sector was based on the country surveys conducted in Chad, DRC, Ghana, Nigeria, Kenya, Uganda and United Republic of Tanzania. The surveys analysed regulatory aspects related to antibiotics, antimalarials and IVDs *(2)*. The analysis classified the primary sources of care into four groups: public sector, licensed pharmacies, accredited drug shops and informal private sector outlets. Fig. 7 shows the primary sources of care according to the surveys. For example, in Nigeria, accredited drug shops

and the informal private sector were the primary sources of care, whereas in Kenya, it was the public sector, licensed pharmacies and informal private sector.

Fig. 7. Primary source of care in the seven countries



All the countries have regulations in place for ACTs and IVDs, but legislation and regulatory bodies for IVDs are still evolving. Countries still lack the capacity to fully enforce the regulations and controls, especially for post-marketing surveillance. This means that practice, especially around diagnostic testing and prescription of antibiotics, is often inconsistent with laws and regulations.

All countries (except for Chad) have some plans for regulating PMRs. Ghana, Nigeria and United Republic of Tanzania already have a system of accreditation for drug stores in place (see next section). However, the surveys and meeting discussions highlighted the presence of regulatory restrictions that need to be overcome in order to ensure that PMRs can provide access to quality malaria case management.

The countries differed in the risk classifications for ACTs and antibiotics, as shown in Table 1.

Table 1. Risk classifications for ACTs and antibiotics in seven participating countries

Country	ACTs	Antibiotics
DRC	OTC	POM
Ghana	OTC	POM
Kenya	POM	POM
Nigeria	OTC	POM
United Republic of Tanzania	AL = OTC, all others = POM	Amoxicillin = OTC, all others = POM
Uganda	AL = OTC, all others = POM	Amoxicillin = OTC, all others = POM

Note: OTC = over-the-counter; POM = prescription-only medicine; AL = artemether-lumefantrine

Within these classifications, the countries also differed in terms of which types of health care professionals (doctors, pharmacists, nurses, midwives, etc.) are allowed to sell and prescribe these drugs. Together with client expectations, the difference in risk classifications between ACTs and antibiotics is a significant barrier in providing appropriate care for non-malarial febrile illnesses, including pneumonia, in the event of a negative malaria diagnostic test result.

In all seven countries, there are also restrictions as to what types of facilities are allowed to perform mRDTs (see Table 2[6]).

Table 2. Where and by whom mRDTs can be distributed/performed/sold in the seven countries

Country	Premises where mRDTs can be administered	Professionals permitted to perform mRDTs	Professionals permitted to sell mRDTs
Chad	Health centres Clinics Private laboratories	All health care workers (incl. CHWs)	Accredited pharmacists
DRC	Hospitals Clinics Registered pharmacies with accredited pharmacists	Accredited pharmacists CHWs	Accredited pharmacists
Ghana	Hospitals Clinics Pharmacies Accredited drug stores	All health care workers in the formal sector	All health care workers in the formal sector
Kenya	Community level Level 1–3 health facilities	Laboratory technicians CHWs	Hospitals Pharmacies
Nigeria	Pharmacies Clinics Dispensaries Hospitals Accredited drug stores	All formal health care workers	Staff in PPMVs, pharmacies, clinics, dispensaries, hospitals
United Republic of Tanzania	Formal health facilities Clinics Private laboratories	Health laboratory practitioners People with specialized training (incl. licensed registered drug shops staff and CHWs)	People registered with the Tanzania Food and Drugs Authority, including ADDOs
Uganda	Hospitals Clinics Pharmacies Accredited drug stores Private diagnostic facilities	Health laboratory practitioners People with specialized training	Pharmacists Pharmacy technicians Nurses

WHO is supporting Member States to strengthen their NRAs in order to ensure access to affordable medical products that are safe, good quality and effective for all diseases. WHO's work to help countries improve their regulatory strengthening efforts involves the benchmarking of NRAs, formulation of institutional development plans, provision of technical support and training, and monitoring of progress and impact. These activities are supported by a coalition of interested parties (CIP). WHO also coordinates the Global Surveillance and Monitoring System for Substandard and

[6] The exact legal designations are not used in the table for the sake of simplicity and for ease of comparison.

Falsified Medical Products, in which ACTs rank second only to systemic anti-infectives in the number of reports to WHO.

There was general agreement that there is still a lot of work to be done to ensure that regulations are aligned with the vision of improving access to quality malaria case management in PMRs. The challenge is that malaria treatment is effectively an OTC market, whereas diagnostic testing and antibiotic treatment are restricted in many countries to the formal medical health care system (public and private).

It was agreed that investing in good regulatory practices, flexible regulatory frameworks that can respond to the particular needs and circumstances of each country, and robust enforcement should be a high priority for national health budgets.

Key Conclusions

- There is a lack of proper alignment in most countries between the regulations that govern the availability of antimalarial drugs and diagnostic testing in PMRs. This needs to be corrected to ensure that PMRs can administer proper care management legally.
- The regulatory framework also needs to encompass case management of non-malarial febrile illnesses, especially those that need to be treated with antibiotics.
- Investment in good regulatory practices, flexible frameworks and robust enforcement should be a high priority.

Accreditation programmes

Three of the countries present at the meeting have accreditation systems in place for drugstores and similar second-tier PMRs. These are:

- Ghana: OTC Medicine Sellers (OTCMSs)
- Nigeria: Patent and Proprietary Medicine Vendors (PPMVs)
- Tanzania: Accredited Drug Dispensing Outlets (ADDOs)

The Tanzanian ADDO system was launched in 2003. Its goal is to improve access to affordable, quality medicines and pharmaceutical services in drug shops in rural or peri-urban areas where there are few or no registered pharmacies. To achieve this goal, the ADDO model takes a holistic approach that develops the capacity of owners and dispensers who work in retail drug shops, as well as the institutions that regulate them. For shop owners and dispensing staff, this is achieved by combining training, incentives, consumer pressure and regulatory enforcement with efforts to influence client demand for and expectations of quality products and services. The benefit that the ADDO owners value the most is the training *(12)*. The system achieved nationwide scale-up in 2013 when 60% of all drug shops were accredited *(13)*. By 2016, over 9000 shops were part of the system and over 19 000 dispensers had been trained. ADDOs have been used as a platform for public health interventions, including to increase access to ACTs for malaria, and they have been incorporated into multiple public health strategies, from family planning to achievement of the Millennium Development Goals *(12).*

Both the Ghanaian and the Nigerian systems are broadly similar in terms of the design of the programme and the types of products that can be sold in the OTCMSs and PPMVs, respectively, but the programmes differ in their details.

In Nigeria, there are 120 000 drugstores, of which about 40 000 are registered as PPMVs with the Pharmacists' Council of Nigeria. Unfortunately, unregistered drugstores usually operate in remote areas, making training, supervision and enforcement difficult.

In 2019, there were approximately 10 000 OTCMSs in Ghana, regulated by the Pharmacy Council. As described in the next section, the private retail sector has been an important part of the successful implementation of the WHO-recommended treatment for paediatric diarrhoeal diseases.

The ADDO model has been shown to be scalable, sustainable and transferable to other countries *(13)*. Accredited drug shops have been shown to be of value in introducing new case management approaches more widely (e.g., in the introduction of zinc/oral rehydration salts (ORS) for diarrhoeal disease in Ghana or ACTs for malaria in United Republic of Tanzania). Accreditation, if supported by the necessary BCC programmes to communicate its objectives, is an indication of quality to the general public and so can increase business for the accredited PMRs. However, studies on appropriate case management have been limited and have produced mixed results.

Learning from other disease programmes

Caring for the sick child: Data from the USAID SHOPS Plus project indicate that globally 42% of caregivers rely on the private sector for care of their sick children. Among private sector users, approximately 36% use pharmacies or drug shops and 14% use informal PMRs. This extends to all economic groups, with 40% of the poorest relying on the private sector for initial care *(4)*.

The SHOPS Plus[7] project seeks to catalyse public–private engagement to improve family planning, HIV/AIDS, maternal and child health, and other public health priorities. From its work in improving the integration of PMRs into national health care systems, the project has identified the following key lessons:

- The key to successful integration is to obtain the buy-in of all sectors through continuous engagement (public sector, donors, implementing partners, civil society, and the private sector).
- The size and scope of the private sector is often poorly understood, and a proper evaluation of this needs to be done at the outset of any engagement programme.
- Government stewardship and ownership of the integration is vital for success.
- Engagement is best achieved by identifying a lead focal point organization within both the public and private sector. This might be a Pharmacy Council, a specific department in the Ministry of Health such as a public–private partnership unit, or a pharmacy trade association.
- Policy and regulatory barriers limit the integration of drug shops into the general health care system.
- Policy is often focused only on the sale of medicines and is "silent" on the provision of services (such as diagnostic testing, counselling and referrals).
- Training and supervision need to be properly designed with private sector needs in mind (e.g., the timing of sessions outside of peak business hours).
- Addressing the customers' influence on prescription decisions and changing their behaviour is also essential to successful integration. Consumers have been shown to have a greater influence in PMRs for three reasons:

[7] See https://www.shopsplusproject.org/

- Staff in PMRs have less depth of knowledge and so are less confident in giving advice to customers compared to pharmacists and staff in hospitals and clinics.
- Customers also view staff as less knowledgeable and so are less willing to accept their advice.
- PMRs need to keep their customers satisfied in order to sustain their business and so may prefer to defer to customers' preferences.

In Ghana, 40% of caregivers seek care for their sick children in the private sector. Of those, 76% seek care in PMRs. The SHOPS Plus project in Ghana has successfully "moved the dial" in the treatment of paediatric diarrhoea away from the use of antibiotics and towards the WHO-recommended treatment of zinc plus ORS. SHOPS Plus worked closely with the Pharmacy Council and the Ministry of Health to design and deliver the relevant training, BCC and regulatory changes to make the programme a success (see Fig. 8).

Changing customer behaviour was achieved by BCC directed at the consumer through the media and/or by strengthening PMR staff's knowledge and confidence in giving advice to consumers. This was also reinforced by appropriate communications materials for display in PMRs and other medical facilities.

Fig. 8. Result of the implementation of the SHOPS Plus Diarrhoeal Treatment Programme in Ghana

The project was launched in 2012 with training programmes. As shown in Fig. 8, the programme resulted in increases in the recommendations of zinc and ORS. Most significantly, there was a sharp drop in the recommendation of antibiotics for childhood diarrhoea.

TB "public–private mix": TB is the top infectious disease killer globally, with 2.6 million deaths in 2017. TB is responsible for high mortality in people living with HIV and is a leading cause of antimicrobial drug resistance. However, a major challenge to reducing the global TB burden is finding all the patients who have contracted TB and initiating them on treatment. In the United Republic of Tanzania, it is estimated that 56% of new infections are not detected (85 000 in 2017); yet, of patients who were put on first-line treatment, 90% were treated successfully.

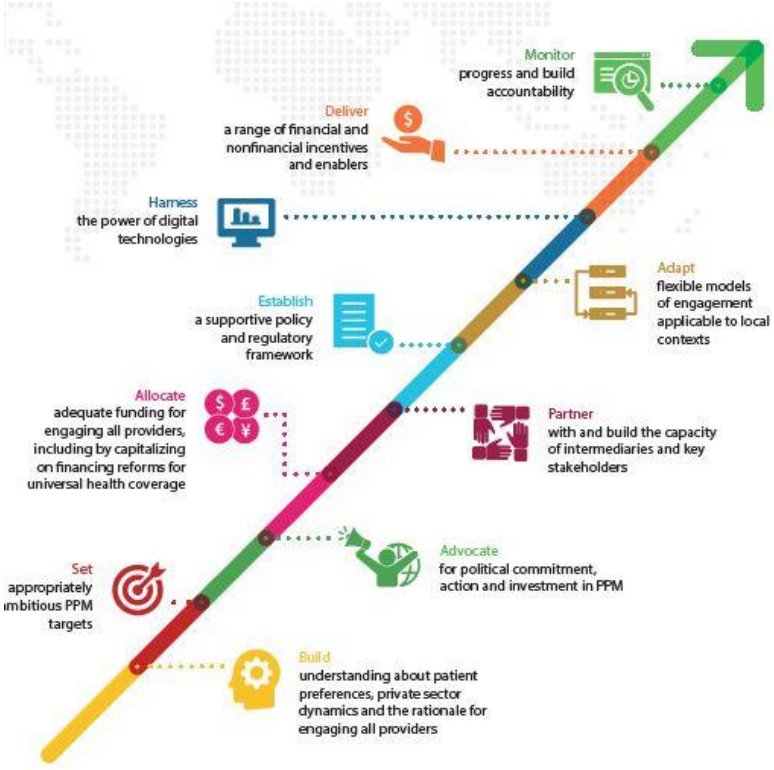
Private health care dominates in many high-burden countries, and so a large proportion of the "missing cases" are seeking treatment in this sector. WHO estimates that in the seven countries with 62% of the "missing cases", private providers account for 65–85% of initial care-seeking by people with TB, but these providers only contribute 19% of TB notifications.

Therefore, engaging with the private sector (which, in this case, includes private hospitals and clinics) is crucial to finding the "missing" people with TB and putting them on treatment. In the United Republic of Tanzania, the national strategic plan has a target to engage 50% of private health facilities (hospitals, clinics, PMRs) in TB services by 2020. They should then be contributing 25% of case notifications (vs. 5% in 2014).

Engagement in TB services is centred on training PMR staff to recognize the signs of TB and refer the patient to an appropriate medical facility for proper diagnosis and treatment. PMR staff usually have a low awareness of TB, its signs and symptoms. Other necessary actions are to ensure that the regulatory environment is aligned with the engagement programme and that the PMRs have the necessary financial and non-financial incentives to engage.

With PMRs (ADDOs in the United Republic of Tanzania), the focus is on engaging them in case referrals, not in treatment. As such, the role of PMRs differs in malaria case management. Malaria is often an OTC market in SSA and thus there is an additional focus on ensuring that quality-assured antimalarials are available in a way that crowds out poor-quality or inappropriate drugs.

Fig. 9. WHO TB public–private mix (PPM) roadmap priorities for action



WHO has published a roadmap for developing private sector engagement and building a "public–private mix" for TB *(14)*. Fig. 9 shows the priorities for action articulated in the roadmap.

Opportunities and concerns for the future

The survey of FLBs in Ghana, Kenya, Nigeria, United Republic of Tanzania and Uganda was completed a few months before the meeting. FLBs were able to provide their perspectives on increasing the availability of QAACTs and mRDTs in the private sector. At the meeting, panels of ACT manufacturers and mRDT manufacturers also discussed this issue.

Availability and access – ACTs

FLBs expressed concern over the reduction in support for co-payment systems in several countries. The AMFm and Global Fund CPM have been successful in both increasing the market share and reducing the price of QAACTs (Figs. 10 & 11).

Fig. 10. QAACT market share

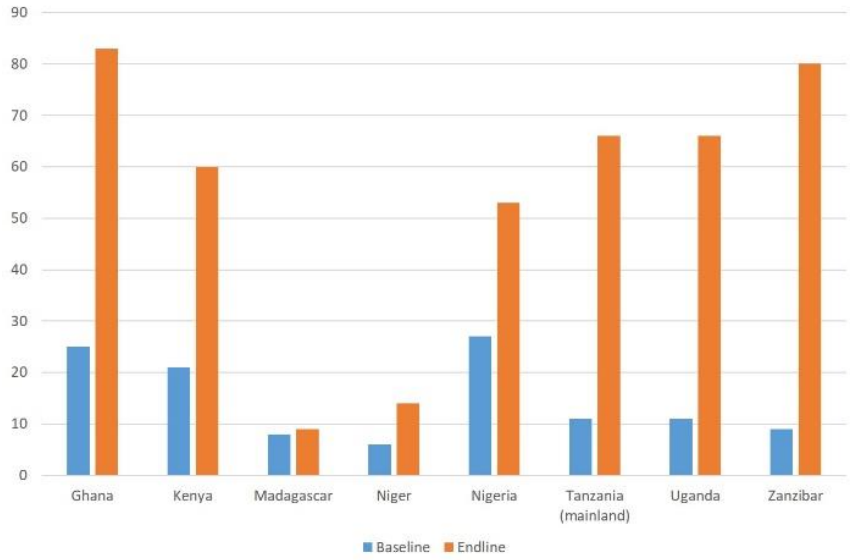
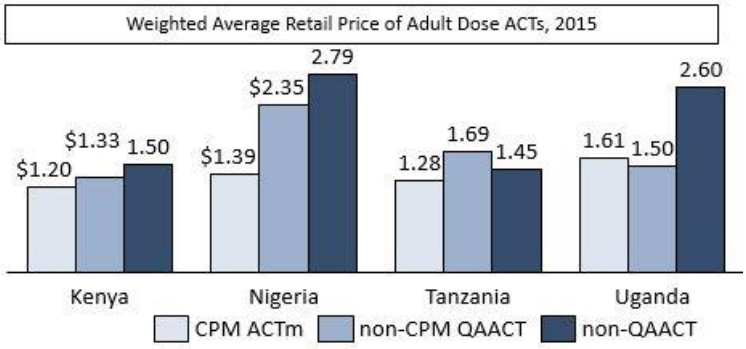


Fig. 11. ACT pricing



Since 2017, the CPM has been terminated in Nigeria and is being reduced significantly in Kenya and Uganda. For QAACTs no longer supplied through the CPM, the import costs have increased and are now higher than for non-QAACTs (Fig. 12). Importers estimated that non-QAACTs cost 20–50% less than QAACTs not supplied through the CPM. Because 70–90% of the market is price-sensitive, this may mean a shift to non-QAACTs.

Importers fear the following outcomes:

- Suppliers will now reduce the number of importers that they work with and this will reduce availability and access.
- Waivers of import duties that applied under the CPM will be removed and this will further increase prices.
- Customers may not be able to afford unsubsidized imported QAACTs because of the high cost of distributing to rural areas, and access to medicines in rural areas will suffer.

Fig. 12. ACT importers' costs

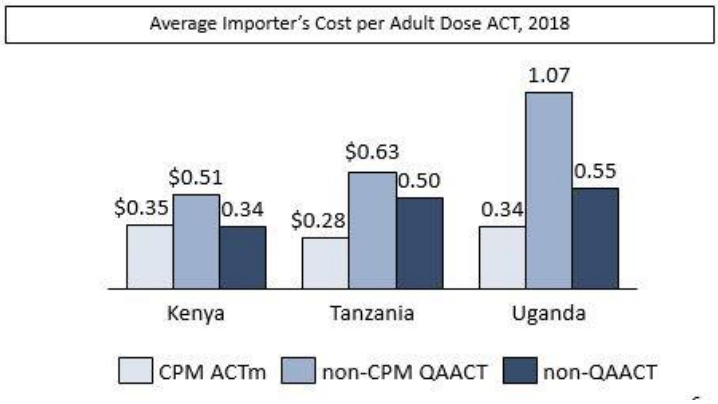
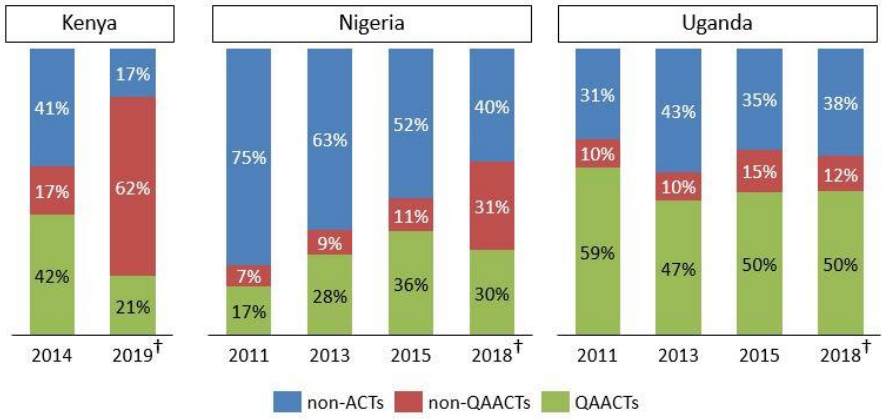


Fig. 13. Market share of QAACTS, non-QAACTs and non-ACTs (all shops)



ACTwatch and CHAI have also carried out market surveys to evaluate the impact of CPM implementation. They have shown that in Nigeria and Kenya the use of non-QAACTs has expanded at the expense of QAACTs (Fig. 13).

It is important to note, and encouraging, that thus far there has been no increase in the market share of non-ACTs.

Product quality - ACTs

The findings on how the relative market shares of QAACTs and non-QAACTs have changed following discontinuation of the CPM have raised questions about the quality of ACTs that are becoming increasingly available in countries, compared to ACTs that are SRA-approved or WHO-prequalified. CHAI is currently testing samples collected in Kenya, Nigeria and Uganda to evaluate this issue.

This in turn has raised concerns about the use of the term "quality-assured" to describe medical products that are procured by international donors (e.g., the Global Fund) based on SRA approval or WHO prequalification.

Several participants at the meeting believed that many of the pharmaceutical products and diagnostic devices that are registered and available in countries have been manufactured to country-specified quality standards, but have not been submitted for approval to an SRA or WHO-PQ. There was general consensus that the term QAACT should not only be used to denote ACTs that are SRA-approved or WHO-prequalified; the lack of such approval should not be an indication that products

are of unacceptable quality at the country level. They argued that products that have been approved by an NRA should also be considered quality-assured, and countries need to strike a balance between quality assurance and increasing access by increasing the number of products available on the market.

Strengthening the regulatory agencies – especially the inspection and enforcement arms – could increase access to more quality-assured medicines and diagnostics at competitive prices for use by NMCPs.

Fig. 14. AMFm Green Leaf logo

ACT manufacturers who participated in the panel discussion were very clear on the need to maintain the promotion of high quality standards, but that this should be supported by efforts to make the drugs affordable, especially in rural areas. The AMFm Green Leaf logo (Fig. 14) has played a significant role in enabling customers to identify quality products. However, counterfeiting of the logo has increasingly become a problem. Manufacturers were at pains to emphasize that fair pricing should recognize costs for manufacturing at quality standards and be factored into new initiatives involving procurement of medical products. Pricing also needs to be sustainable for manufacturers over the medium to long term in order to ensure that there are multiple suppliers and competition in the market.

Expanding the market - mRDTs

mRDT manufacturers on the panel were concerned about the level of attention paid to QAACTs – their price, quality, market share, etc. – and the comparative lack of attention paid to the promotion of testing before treatment with mRDTs.

There is a need to establish protocols to enable PMRs to manage patients appropriately if they test negative for malaria. In the absence of such protocols, there is evidence that diagnostic testing for malaria may reduce incorrect treatment with antimalarials but increase the inappropriate use of antibiotics.

Several other issues were raised:

- Complexities in the supply chain (e.g., licenses, approvals and tariffs) add to the cost of the tests when they reach the end-user. Simplification may help to keep the cost down.
- The supply chain has too many layers where margins accumulate and further add to the end-user cost.
- PMRs should make a decent return on testing while addressing the need to maintain affordability of the Test, Treat and Track strategy[8]. Ideally, the costs of testing and treatment should be the same, regardless of the test results.

[8] https://www.who.int/malaria/areas/test_treat_track/en/

- There is a need to change customer expectations and behaviours about testing and receiving drugs when visiting a shop.[9] This underlines the importance of governments and NMCPs in terms of generating demand for testing and educating the general population about the Test, Treat and Track strategy. If there is demand, then manufacturers will meet it.
- There is a need to ensure that there is a proper training and accreditation system in place for PMR staff to be able to safely and effectively perform tests in shops, observing blood safety requirements. The system needs to be regularly followed up to ensure standards are maintained.

Key Conclusions

- Countries have started to reduce or terminate use of co-payments under the Global Fund CPM system due to other priorities. There is initial evidence that reduction or termination of co-payments will produce a shift to the use of non-QAACTs in PMRs. There is no evidence yet showing a shift back to other antimalarials (non-ACTs) to treat malaria.
- The definition of a QAACT often used by global agencies (e.g., the Global Fund, USAID) to indicate an ACT that is SRA-approved or WHO-prequalified should be abandoned. There are ACTs available on the market that are quality-assured but have not been submitted for approval to an SRA or WHO-PQ.
- Manufacturers are keen to clarify that quality comes at a cost and pricing needs to reflect the manufacturing requirements to supply quality products consistently. This will ensure a competitive but sustainable market in the medium to long term.
- Proper protocols need to be put in place to guide PMR staff in the event of a negative mRDT result in order to ensure appropriate application of the Test, Treat and Track strategy.
- Ongoing BCC is needed to change the expectations and behaviours of the general population when visiting PMRs to seek treatment for fevers.
- PMRs need acceptable profit margins for performing mRDTs (and other diagnostic tests). In order to support the implementation of the Test, Treat and Track strategy, the cost to patients/caregivers should ideally be independent of the mRDT test result.

Key themes across countries

Although the findings from individual countries differed, certain key themes emerged. To develop proper country analyses and plans, more work is needed in each country with all stakeholders using the PSI "Keystone Design Framework" or other similar planning approaches.

[9] This challenge is outlined in the discussion of the SHOPS Plus programme in Ghana.

Common Vision

There was general consensus on the vision for the role of the private sector in case management:

- All patients, irrespective of their social status and where they live, have the right to access quality malaria case management.
- As many patients seek treatment for febrile illness first through the private sector, this sector must be able to deliver quality malaria case management.
- Private sector health care providers need to be considered an integral part of a country's national health system.

Key Themes

- **Promotion:** Governments, NMCPs and other key stakeholders need to generate demand among the population for better quality care in the private health sector. BCC activities targeting the general public need to continue to promote malaria diagnostic testing and compliance with the results.
- **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector must be raised through:
    - accreditation systems for drug shops;
    - training in malarial and non-malarial fever case management and professional development schemes for private health care providers;
    - supervision of private health care providers, ideally by existing government health care workers;
    - increasing the availability and affordability of quality diagnostics and medicines.
- **Policy and regulation:** Country policies and regulations should be reviewed and revised so as to support the implementation of appropriate case management.
    - There needs to be clarity and consistency of the policies and regulations on where and by whom mRDTs can be performed, and who can prescribe and/or sell antimalarials and where.
    - Policy makers and regulators should be aligned on the technical specifications required for health products (diagnostics and medicines).
    - Policies and regulations that support the extension of quality malaria testing services should be coupled with appropriate treatment.
    - There needs to be robust supervision and regulatory enforcement supported by training and follow-up programmes.
- **Market information:** The lack of detailed information on the private sector market, especially outside the large urban areas, should be addressed and results should be disseminated to all stakeholders so as to inform interventions aimed at improving access to

quality malaria care in the private sector. As countries differ, each needs to undertake an in-depth market review.[10]

- **Surveillance:** Simple systems should be developed to allow the private sector to be fully integrated into national surveillance systems.
- **Pricing and incentives:** Countries should ensure that:
    - the pricing of quality-assured products supports the crowding out of poor-quality or inappropriate products;
    - the cost to the caregiver/patient of the testing and treatment package is affordable and promotes the Test, Treat and Track strategy;
    - tax and tariff systems are aligned so that diagnostics are not disadvantaged compared to medicines.
- **Coordination:** Different stakeholders are not always aligned on the best way to involve the private sector in delivering quality case management of malaria. It will be necessary to bring all stakeholders together to develop a coordinated approach.[11]

Support and guidance needed from WHO

The meeting also concluded that WHO could assist countries in integrating the private sector into the delivery of quality malaria case management. The following specific actions were recommended.

Advocacy

The consideration of the private sector as an integral part of the health care delivery system by the NMCPs can be used as a pilot leading to wider recognition of the private sector as an essential platform for delivering universal health coverage (UHC). Unfortunately, in many countries, such efforts are often not high priority and are often crowded out by other public health priorities. It would help for WHO to advocate widely for a strong, appropriate role for the private sector.

It would also be particularly useful for WHO to make the case for strong private sector engagement to heads of government (HoGs). Many of the issues constraining the proper integration of the private sector into the health care system will require cross-government collaboration (e.g., alignment of tax and tariff treatments between mRDTs and ACTs will require participation of the Ministry of Finance). Advocacy could also be carried out through organizations like the African Leaders Malaria Alliance or Asia Pacific Leaders Malaria Alliance in their dialogues with HoGs.

WHO can also assist in involving other organizations, such as the RBM Partnership to End Malaria, and key international donors (Global Fund, USAID, UK DFID, Unitaid, Foundations, etc.) in advocacy and the development of initiatives to support the full integration of the private sector into malaria case management.

Private sector engagement

Sharing the lessons gained from private sector engagement with other diseases (e.g., the public–private mix for TB, SHOPS Plus project) would assist countries in identifying and overcoming challenges. In addition, countries would like to see more guidance on ways to better engage the private sector in delivering quality case management and to properly implement the Test, Treat and

[10] This was also a key recommendation from the SHOPS Plus project in Ghana.

[11] This was also a finding from the SHOPS Plus project in Ghana.

Track strategy. Countries need shared lessons and best practices along with research on how to make private sector engagement attractive both financially and non-financially.

Guidance from WHO on the best ways to strengthen the oversight of the private sector by the public sector would also be welcome.

WHO could also play a role in linking NMCPs to broader conversations about UHC and the potential contribution of the malaria private sector strategy.

Furthermore, WHO could use its convening power to facilitate discussions among all national stakeholders (e.g., Ministry of Health, NRA, Medical Council, Pharmacy Council, drugstore owners' industry association, etc.).

Resourcing

When budgets are set and donor funding is sought, initiatives to support the private sector (e.g., the CPM for ACTs) can get crowded out by other public health projects. Countries need guidance on the best way to prioritize funding needs in order to ensure that private sector initiatives receive the level of resources appropriate for delivering quality case management.

Negative test results

There is an urgent need for recommendations on the correct protocol for PMRs to follow in the event of a negative test. Such recommendations should recognize the pressures on PMRs, both financially and from patients/caregivers, to provide treatment even in the event of a negative mRDT result, rather than referring the patient to a public health facility.

Affordability

Key barriers to the proper implementation of the Test, Treat and Track strategy in the private sector are how to make the package affordable to caregivers/patients and how to promote testing before treatment. WHO should carry out more work at the global and regional level to identify approaches to overcome these barriers.

Promoting innovation

There is still a need for improved diagnostic tools that can distinguish between malaria and other causes of fever and that are appropriate for the private sector context.[12] In addition, there is a need for data capture tools (e.g., through mHealth technologies) that can be used in the private sector to allow it to play a full role in national surveillance systems. Countries would welcome WHO's continued support and advocacy for work on these innovations.

Technology transfer

WHO should support technology transfer to promote local manufacturing of ACTs and mRDTs so as to increase the supplier base and, by increasing competition, drive down prices.

[12] FIND has a disease programme looking at this (see https://www.finddx.org/mal-fev/).

Key Requests

- **Advocacy:** Advocate for the importance of the private sector in order to ensure that quality case management is available to all, as an essential component of achieving UHC.
- **Support and guidance**: Provide support to governments (including sharing best practice) on how best to engage the private sector in terms of:
    - facilitating cross-sectoral coordination through country-based forums;
    - making investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.
- **Quality case management:**
    - Provide guidance on how to assess the quality of care in the private sector, not just the quality of health products.
    - Ensure continued promotion of appropriate use of malaria diagnostics in order to deliver quality care for febrile illnesses in malaria-endemic countries.
    - Make recommendations on the correct protocols to follow in the event of a negative mRDT, acknowledging the actual pressures on the ground.
- **Affordability:** Based on a range of business models/pricing strategies, make recommendations on how quality case management can be made affordable to patients, while ensuring a reasonable return to private health care providers.
- **Innovation:** Develop innovative systems and incentives to promote reporting from the private sector and to integrate the sector into national surveillance systems.
- **Local manufacturing:** Support technology transfer in malaria-endemic countries in order to increase local production of ACTs and mRDTs that meet the quality requirements needed for procurement with international funds.

Ideally, this guidance should be brought together into a **Roadmap** (similar to the TB Roadmap) for integrating the private sector into national strategies to improve malaria case management. This guidance should provide direction to ministries of health and other national agencies on how best to engage with the private sector, especially PMRs, to deliver proper diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.

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Annex 3: Agenda

Wednesday 1 May 2019		
9:00 - 9:15	Welcome and opening remarks	P. Alonso
9:15 - 9:30	Objectives of the meeting	A. Bosman
Session 1 – What is known on malaria case management in the private sector		
9:30 - 9:45	Results from DHS/MIS surveys in high-burden countries	J. Aponte
9:45 - 10:20	Review of evidence on improving malaria case management by private-sector providers	C. Goodman & T. Visser
10:20 - 11:00	Discussion	
11:20 - 12:20	ACTwatch, AMFm/CPM, ADDO programme & Unitaid RDT project Panellists: S. Poyer, C. Goodman, E. Shekalaghe & N. Charman	R. Orford (moderator)
12:20 - 13:00	Discussion	
Session 2 – Laws, regulations and policies influencing malaria case management in the health sector		
14:00 - 14:40	Survey tool and comparative analysis of policies and regulations that affect malaria case management in the private sector in Chad, DRC, Ghana, Kenya, Nigeria, United Republic of Tanzania and Uganda	T. Visser
14:40 - 15:30	Discussion	
16:00 - 16:20	WHO assessment of national regulatory authorities	H.B. Sillo
16:20 - 16:50	Market survey in Kenya, Nigeria, United Republic of Tanzania and Uganda following interruption of Global Fund Co-Payment Mechanism (CPM) in 2018	A. Woolsey J. Tibenderana
16:50 - 17:10	WHO surveys of spurious, falsified and substandard antimalarial medicines	M. Deats
17:10 - 17:30	IQVIA market intelligence	D. Batra
17:30 - 18:15	Discussion	
Thursday 2 May 2018		
Session 3 – Relevant lessons learned by other public health programmes		
8:30 - 9:20	Tuberculosis programme for public–private mix to improve case management in private sector	H.M. Dias A. Tarimo
9:20 - 10:10	Family-planning and IMCI experience by SHOPS Plus project for improving case management in the private sector	S. Callahan J.A. Yobo
10:10 - 10:40	Discussion	

Session 4 – Experience of private companies in priming the market in malaria-endemic countries

11:00 - 12:00	Perspectives from manufacturers of prequalified antimalarial medicines and RDTs on priming the market in malaria-endemic countries	Panel session
12:00 - 12:15	Perspectives from FLBs of prequalified antimalarial medicines and RDTs on priming the market in malaria-endemic countries	T. Visser
12:15 - 13:00	Discussion	

Session 5 - A strategic framework for engaging the private sector in malaria case management

14:00 - 14:15	Introduction to the working groups	J. Cunningham
14:15 - 16:00	Working groups (Salle D, D13014, D23015 and other)	
16:30 - 18:00	Working groups, continued (Salle D, D13014, D23015 and other)	
Friday 3 May 2019		
8:30 - 10:30	Working groups, continued (Salle D, D13014, D23016 and other)	
11:00 - 13:00	Presentation of working groups and discussion	Working groups
14:00 - 15:30	Consensus-building on core elements and format of a roadmap to improve malaria case management in the private sector	Chairperson
16:00 - 16:30	Summary of points of agreement	Rapporteur
16:30 - 16:45	Proposed next steps	A. Bosman
16:45 - 17:00	Closing remarks	P. Alonso

Annex 4: Templates used in country breakout sessions

Prioritized Diagnosis Production to Use (P2U) Matrix

	Market Function	RDT Manufacturers	Importers	Wholesalers	Providers	Clients / Consumers
Core Functions	Product					
	Price					
	Place					
	Promotion					
Supporting Functions	Information					
	Coordination					
	Guidance					
	Quality Assurance					
	Financing					
	Labour					
Rules Functions	Policy					
	Regulation					
	Taxes and Tariffs					

Tool 1: Where are we now?

Adapted from: Population Services International (2018). *The Keystone Design Framework Manual.*

Future Vision for Sustainability of High-Quality Private Sector Case Management Market (Who does, who pays?)

			Current State		5 Years (2024)		
Market Function (e.g. Product, Price, Place, Promotion, Information, etc.)	Current Constraint	Long-term vision for the function	Who does?	Who pays?	Who does?	Who pays?	Why?

Adapted from: The Springfield Centre (2015). *The operational guide for making markets works for the poor (M4P) approach.*

WHO Technical Consultation on malaria case management in the private sector of high burden countries

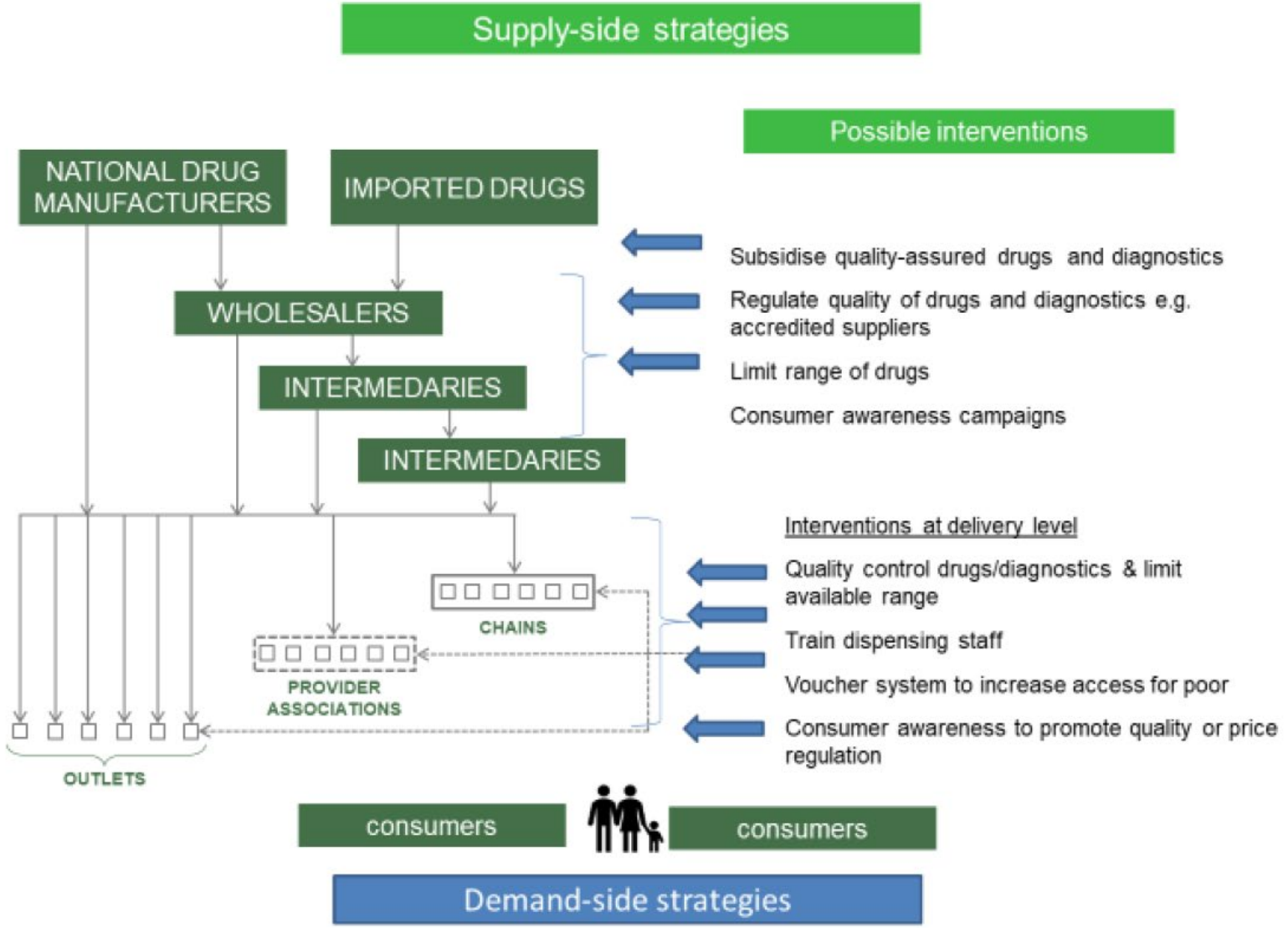
1-3 May 2019, Salle D, World Health Organization, Geneva, Switzerland

Global **Malaria** Programme

World Health Organization

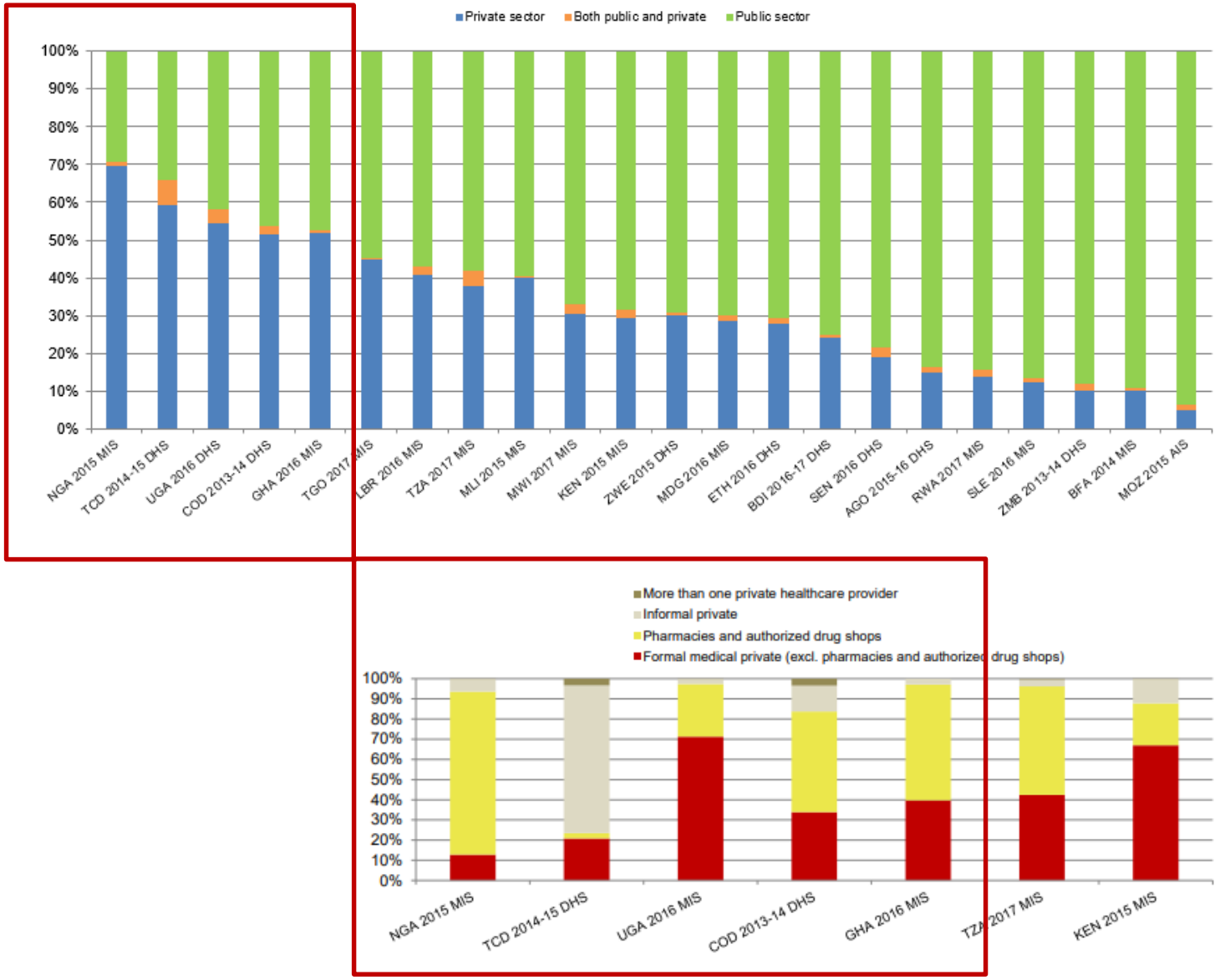
Interventions to improve quality of care in drug shops

Source: HANSHEP*. Engaging the private drug retail sector to make faster progress towards pro-poor Universal Health Coverage in low and middle-income countries. Unpublished report.



* Harnessing non-state actors for better health for the poor https://www.hanshep.org/

Treatment seeking of febrile children in SSA



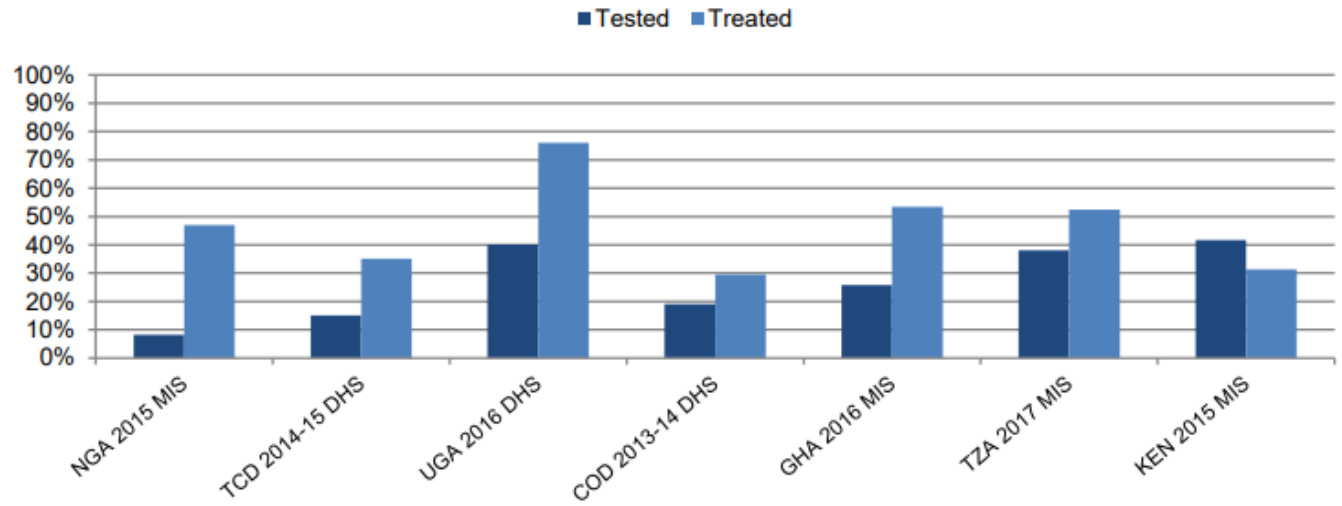
- Preliminary analysis of 22 national-level surveys completed in sub-Saharan African countries between 2014 and 2017 showing first-place of treatment seeking of febrile children.
- In 5 countries, i.e. Nigeria, Chad, Uganda, DRC and Ghana over 50% of the children affected by febrile illness seek first treatment in the private sector. Proportions seeking treatment in the informal versus the formal private sector vary among countries.

Treatment seeking of febrile children in SSA

- With the exception of Kenya, the proportion of febrile children who took antimalarials was systematically higher than those who received a diagnostic test, suggesting that antimalarial treatment continues to be prescribed on the basis of fever without laboratory confirmation in the private sector.

- Based on ACTwatch surveys, the majority of malaria blood tests sold or distributed in private-for-profit medical health facilities were microscopy tests while in pharmacies and drug stores, RDTs were mainly used.

Percentage of febrile children under 5 who received a diagnostic test and who took antimalarials among those seeking care in the private sector, in selected countries, 2014-2017



Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Country codes: COD: Democratic Republic of Congo; GHA: Ghana; KEN: Kenya; NGA: Nigeria; TCD: Chad; TZA: United Republic of Tanzania; UGA: Uganda.

Objectives of the Technical Consultation

1. To review the data supporting the rationale for an international effort to engage private-sector players in malaria case management, and the evidence base that this can be done safely and effectively.
2. To review the laws, regulations and policies influencing the use of medicines and point-of-care diagnostic tests in malaria case management in a set of high-burden countries in Africa.
3. Based on this review, to identify the main bottlenecks and outline steps, including research priorities, to reduce barriers to enable improved quality of care for malaria across the entire health sector.
4. To draw upon documented lessons learned from major global, regional and country initiatives to improve malaria case management in the private sector, including the Global Fund Co-Payment Mechanism, the UNITAID project Creating a private-sector market for quality-assured RDTs, the Accredited Drug Dispensing Outlets (ADDO) project in Tanzania, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) framework for engaging the private sector in malaria case management.
5. To review results of recent private-sector outlet surveys, and the main determinants of supply chain and distribution mechanisms for malaria medicines and diagnostics in the private sector, taking into consideration the experience of pharmaceutical and diagnostic companies in priming the market in high-burden malaria endemic countries.
6. To identify key lessons learned and best practices from other public health programs – including family planning, tuberculosis and HIV – with a long history of private-sector stakeholder engagement.

Process and methods of work

- GMP PDT in collaboration with SEE unit established a multiagency team to support the preparations of the technical consultation, involving Drs L. Barat (USAID PMI), A. Cameron (UNITAID), G. Jagoe (MMV), S. Filler (GFATM), C. Goodman (LSTM&H), R. Orford (PMI Impact Malaria), A. Pratt (BMGF), J. Tibenderana (Malaria Consortium) and T. Visser (CHAI), providing advice on key resources, analytic work and pre-reads.
- The technical consultation involved 70 participants representing NMCP and NRA of the 7 countries, public health experts involved in regulatory reviews, outlet surveys and research on malaria case management and other public health programs in the private sector, including private sector representatives (suppliers of prequalified ACTs and RDTs, and first-line buyers (FLB) involved in Global Fund Co-Payment Mechanism (CPM)).
- CHAI, MC and PSI completed "policy profiles" of the 7 countries on policies & regulations affecting antimalarial medicines, antibiotics, and in-vitro diagnostics. These, their comparative analysis and selected publications were shared as meeting pre-reads, together with results of first-line buyers procuring ACTs via the CPM in Ghana, Kenya, Nigeria, Tanzania and Uganda.
- Using methodology adapted from PSI's "Keystone Design Framework", participants in 7 country teams discussed main market constraints along the supply chain, how to reduce barriers and promote best practice to improve access to quality of care for malaria in the private sector.

Conclusions

Common Vision

- All patients, whatever their social status and wherever they live, have the right to access quality malaria case management.
- As a majority of patients access care for febrile illness first through private sector, this sector must be able to deliver quality malaria case management.
- The private health sector needs to be considered as an integral part of the national health systems.

Objective 1 – current evidence base

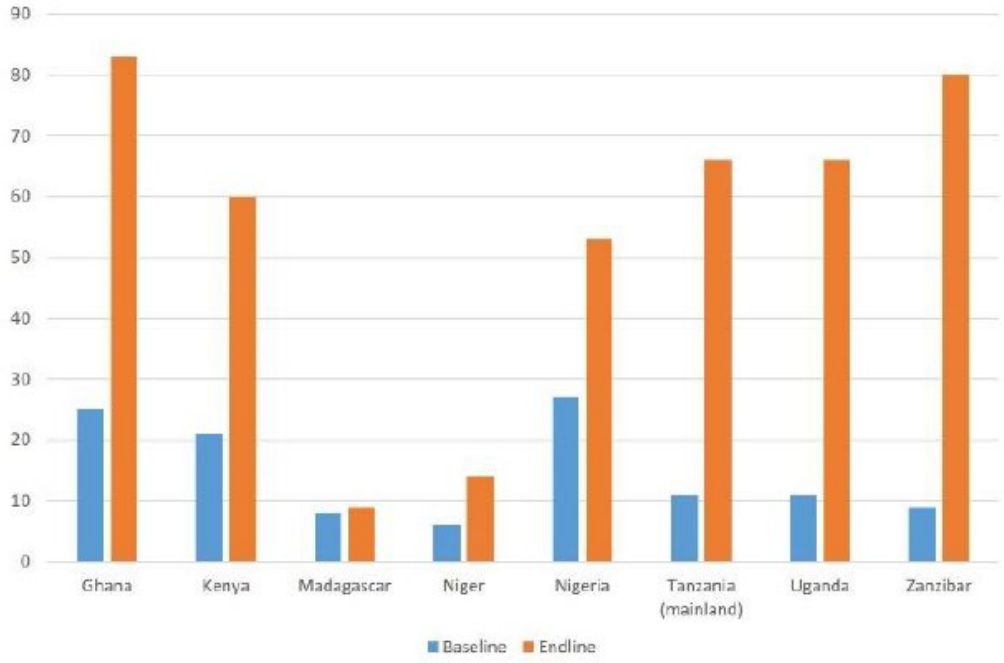
- Limited evidence on different ways to improve case management in the private medicine retail sector (PMRs), consisting of pharmacies, authorized and informal drug shops, and medicine sellers/hawkers.
- To move research and pilot projects to scale, regulatory restrictions on who can test, treat, and sell health products need to be removed/harmonised so that tasks can shift to where patients are accessing care.

<u>Availability & Affordability:</u>

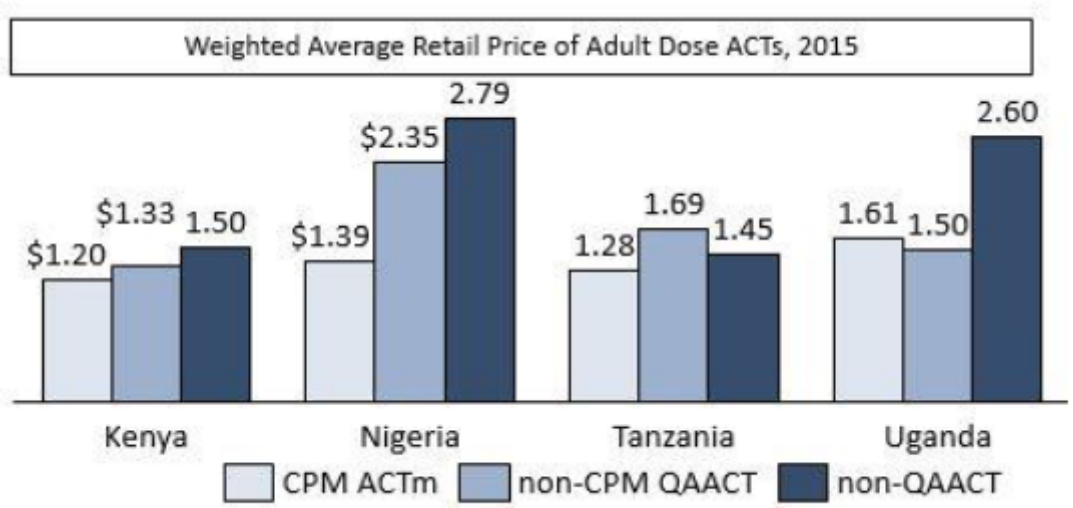
- Lowering purchase cost (through co-payments) of quality-assured antimalarials and diagnostic services or providing quality assured commodities free of charge to providers and patients, together with associated BCC programs, can increase availability and affordability. However, in the absence of pre-treatment diagnostic testing, increased availability and affordability of ACTs leads to a high level of inappropriate treatment of non-malarial fevers.

Impact of global subsidies of QAACTs in the private sector

QAACTs market share in private sector following AMFm



ACTs prices in private sector following GF-CPM



- The AMFm and Global Fund CPM have been successful in both increasing the market share and reducing the price of QAACTs.

Objective 1 – current evidence base

Quality of Care:

- There is limited knowledge on the best way to introduce mRDT testing into PMRs. There is evidence that PMR staff can successfully perform the test and adhere to the results, often better than formal healthcare workers. However, as in the public sector, this needs adequate training and regular follow-up.
- Appropriate protocols for the management of non-malarial fevers are also required, adapted to private sector in limited resource settings

Consumer Knowledge:

- BCC is crucial to change consumer behaviour and expectations when seeking care in the PMRs.
- Existing demand for testing services does not exist everywhere and testing is perceived as a commodity that has to be paid for.

Surveillance:

- There is little experience on developing appropriate surveillance for the private sector, with appropriate tools, incentives, and systems.

Objective 2 – regulation and enforcement

- All countries have regulations in place for ACTs and IVDs, but in some legislation and regulatory policies for IVDs are still evolving.
- Countries still lack the capacity to fully enforce the regulations especially for *post*-marketing surveillance and enforcement of controls. This means that practice, especially around diagnostic testing and the prescribing of antibiotics, is often inconsistent with laws and regulations.
- Countries differ in risk classification of ACTs and antibiotics

Country	ACTs	Antibiotics
DRC	OTC	POM
Ghana	OTC	POM
Kenya	POM	POM
Nigeria	OTC	POM
Tanzania	AL[8] = OTC, all other =- POM	POM
Uganda	AL = OTC, all other = POM	Amoxycillin =OTC, all other =POM

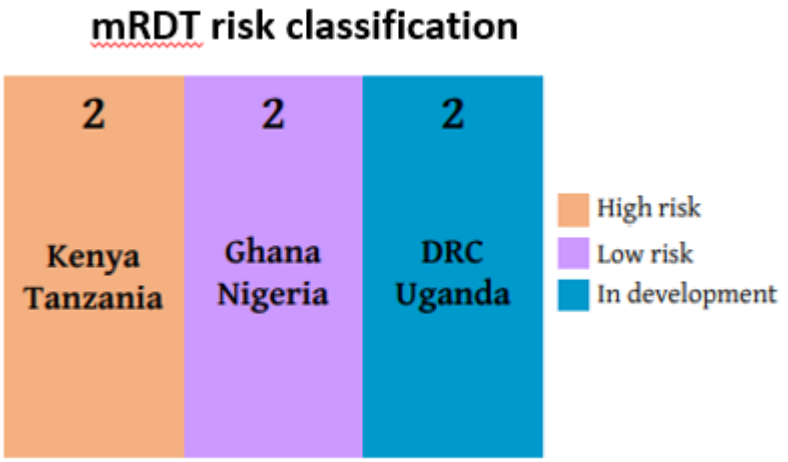
OTC = Over the counter; POM = prescription-only medicine

- Differences in risk classifications between ACTs and antibiotics are a barrier for appropriate care of non-malarial febrile illnesses, including pneumonia, in case of negative malaria test.

Objective 2 – regulation and enforcement

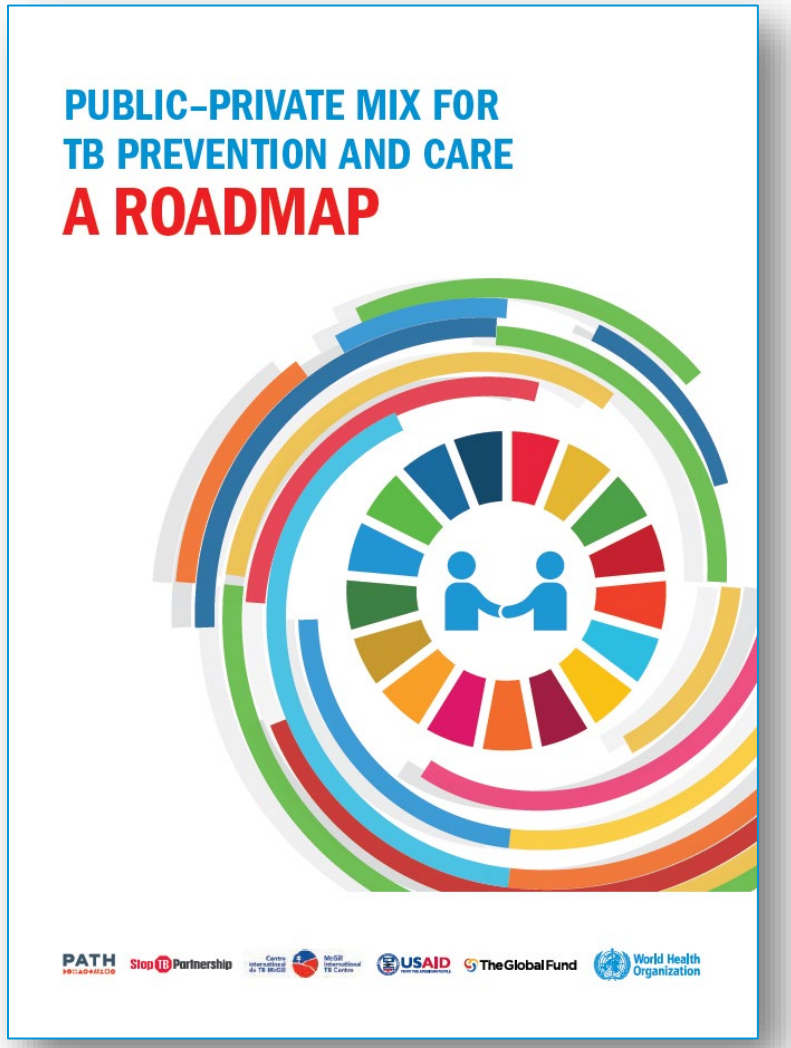
- Countries have restrictions on what types of facilities are allowed to perform mRDTs

Country	Premises where mRDTs can be performed	Professionals permitted to perform mRDTs	Professionals permitted to sell mRDTs
Chad	Health centres, Clinics Private laboratories	All health care workers (including CHWs)	Accredited pharmacists
DRC	Hospitals, Clinics Registered pharmacies with accredited pharmacists	Accredited pharmacists CHWs	Accredited pharmacists
Ghana	Hospitals, Clinics, Pharmacies Accredited drug stores	All health care workers in the formal sector	All health care workers in the formal sector
Kenya	Community level Level 1–3 health facilities	Laboratory technicians CHWs	Hospitals Pharmacies
Nigeria	Pharmacies, Clinics, Dispensaries, Hospitals Accredited drug stores	All formal health care workers	Staff in PPMVs, pharmacies, Clinics, Dispensaries, Hospitals
United Republic of Tanzania	Formal health facilities Clinics Private laboratories	Health laboratory practitioners People with specialized training (incl. licensed registered drug shops staff and CHWs)	People registered with Tanzania Food and Drugs Authority, including ADDOs
Uganda	Hospitals, Clinics, Pharmacies Accredited drug stores Private diagnostic facilities	Health laboratory practitioners People with specialized training	Pharmacists Pharmacy technicians Nurses



- All countries require registration for IVD products.
- None of these 7 countries regulate prices of RDTs
- Taxes on imported RDTs – minimal in Tanzania and Uganda

Objective 6 – lessons from other public health programs



https://www.who.int/tb/publications/2018/PPMRoadmap/en/

Conclusions: emerging common themes

Key Themes

- **Promotion:** Governments, NMCPs, and other key stakeholders need to generate demand for better quality of care in the private health sector in the population. The general public needs to be better educated for behaviour change on the need for malaria testing and compliance with results.

- **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector can be enhanced through:
  - Accreditation systems for drug shops.
  - Training in malaria and non-malarial fever case management and professional development schemes for private health care providers.
  - Increasing availability and affordability of quality diagnostics and medicines.

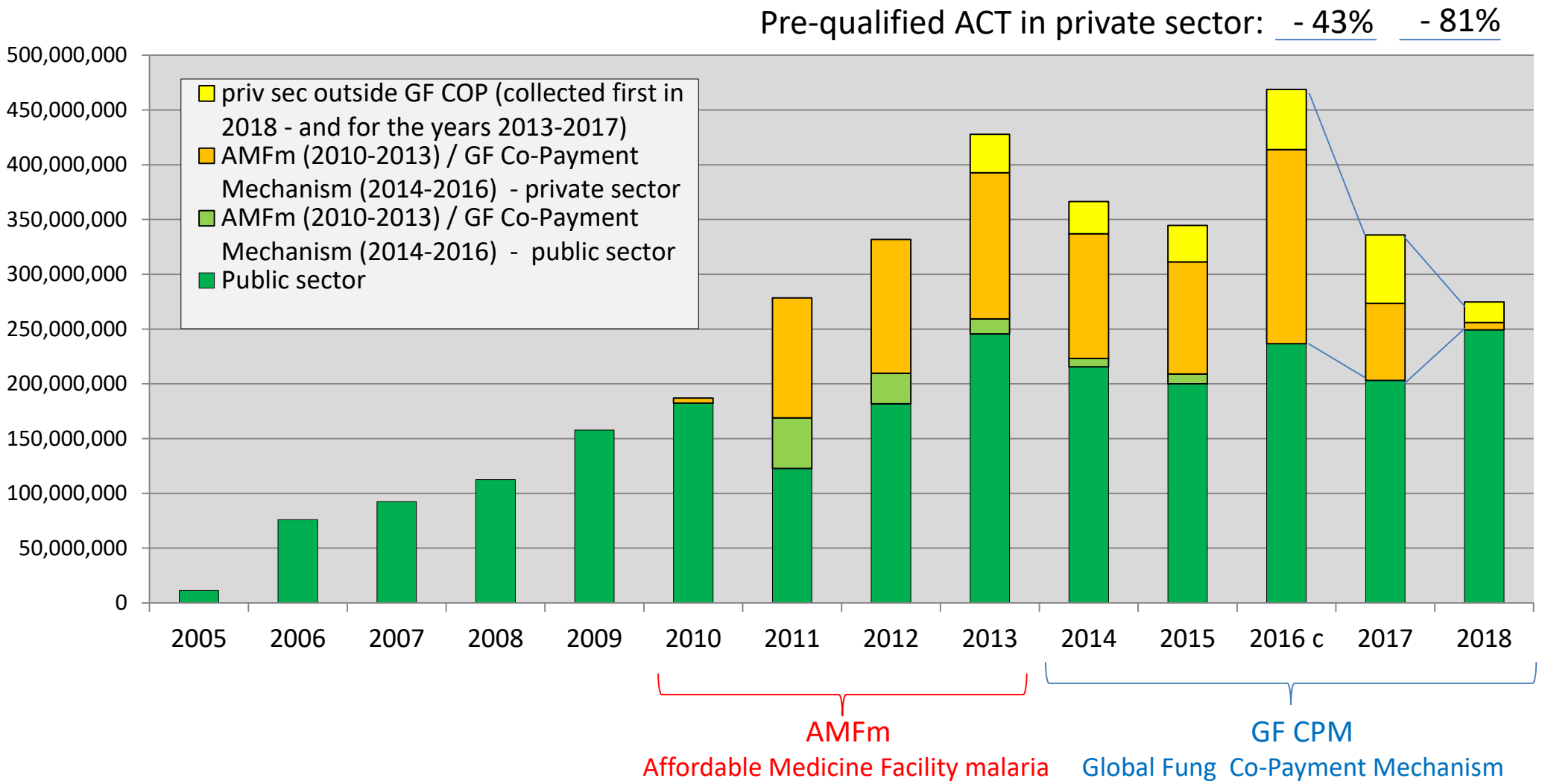
Key Themes (cont'd)

- **Policy & Regulation:** country policies and regulations should be reviewed and revised so as to support the implementation of appropriate case management.
  - Clarity and consistency of policy and regulation on where and who can carry out the malaria rapid diagnostic testing and where and who can prescribe and/or sell antimalarials.
  - Alignment of policy makers and regulators on technical specifications requirements for health products (diagnostics and medicines).
  - Policies and regulation that support the extension of quality malaria testing to ensure rational use of malaria medicines.
  - Develop guidance and promote behaviour change to ensure that health care providers and patients know what should happen in the event of a negative malaria test result.
  - Robust supervision and enforcement of the regulations supported by training and follow-up programmes.

Key Themes (cont'd)

- **Market Information:** address lack of detailed information on the private sector market dynamics, especially outside the large urban areas, and disseminate results among all stakeholders. Each country needs an in-depth market review.
- **Surveillance:** develop simple systems that allow the private sector to be fully integrated into national surveillance systems.
- **Pricing and Incentives:**
  - Ensure that the pricing of quality-assured products supports the crowding out of poor quality or inappropriate products.
  - Ensure that the cost to the caregiver/patient of the package of testing and treatment is affordable and promotes appropriate case management.
  - Ensure that tax and tariff systems are aligned so that diagnostics are not disadvantaged against pharmaceutical products.
- **Co-ordination:** Different stakeholders are not always aligned on delivery of quality case management and how to involve the private sector in this. It will be necessary to bring all groups together to work out ways to overcome this constraint

ACT deliveries by sector: 2005 - 2018



Source: WHO data for WMR2019 from 10 manufacturers eligible for procurement by WHO/UNICEF

Conclusions – further support & guidance

Key requests to WHO

- **Advocacy:** for the importance of the private sector to ensure quality case management is available to all, as an essential component to achieve UHC.
- **Support and guidance**: to governments (including sharing best practice) on how best to engage the private sector:
  - To facilitate cross-sectoral coordination through country based forums.
  - To make investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.
- **Quality case management:**
  - Guidance on how to assess the quality of care in the private sector, not just quality of health products.
  - Continued promotion of appropriate use of malaria diagnostics to deliver quality of care of febrile illnesses in malaria endemic countries.
  - Recommendations on the correct protocols to manage patients with negative mRDT that recognises the actual pressures on-the-ground.

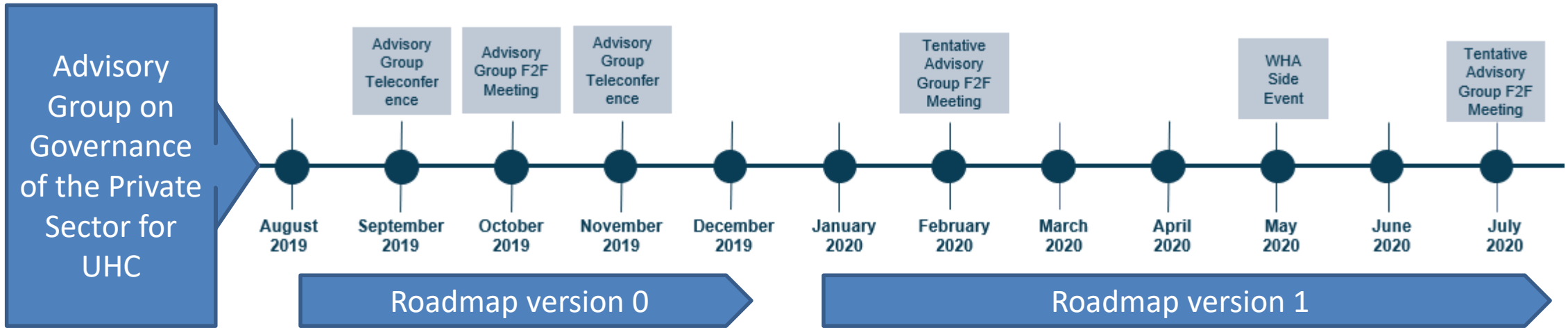
Key request to WHO (cont'd)

- **Affordability:** based on a range of business models/pricing strategies, make recommendations on how proper case management can be made affordable to patients while ensuring a proper return to private health care providers.
- **Innovation:** develop innovative systems and incentives to promote reporting from the private sector and integration into the national surveillance systems.
- **Local manufacture:** Support transfer of technologies in malaria endemic countries to increase the amount of local production of ACTs and mRDTs that meet quality requirements needed for procurement with international funds.

Ideally these should be brought together into a **Roadmap** (similar to the TB Roadmap) for integration of the private sector into national strategies to improve malaria case management. This should provide direction to Ministries of Health and other national agencies on how best to engage with the private sector, especially PMRs, to deliver proper diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.

Proposed next steps

- Support main streaming of private sector intiatives, through WHO internal working group, led by Health Governance and Financing Department.



- Core elements: effective governance of the private sector, maintaining the strategic direction for the health system aligned to UHC values, collecting and using intelligence to correct undesirable trends and distortions, articulating the case for health in national development, exerting influence through regulation and partnerships and establishing transparent and effective accountability mechanisms.
- GMP review of evidence and development of best practice manual for NMCP managers

Many thanks for your kind attention

Malaria Policy Advisory Committee Meeting
2–4 October 2019, Geneva, Switzerland
Background document for Session 6

Technical consultation on institutionalizing Integrated Community Case Management to end preventable child deaths

July 2019

Globally in 2017, 5.4 million children under the age of 5 died *(1)*. Nearly half of these deaths occurred in sub-Saharan Africa. Pneumonia, diarrhoea and malaria remain the main causes of deaths among children aged 1–59 months. Overall, 52 countries are not on track to achieve the child survival target set by the Sustainable Development Goals (SDGs) of less than 25 deaths per 1000 live births by 2030.

Integrated programming approaches implemented at the primary health care (PHC) level have been shown to improve outcomes for key causes of child death, with delivery of key interventions at community level having a particularly strong impact *(2)*. Achieving universal health coverage (UHC) and reaching the child health-related SDG targets will require strong PHC systems and the institutionalization of community health systems.

Community health workers (CHWs) can effectively deliver a range of preventive, promotive and curative health services, contributing to increased access and reduction in inequities. A recent WHO guideline *(3)* has consolidated evidence on optimizing CHW programmes through the identification of effective policy options for selection, education, management, remuneration, system support and community engagement.

Since 2012, WHO and UNICEF have recommended Integrated Community Case Management (iCCM) of childhood illness as a community-level component of a comprehensive strategy for Integrated Management of Newborn and Childhood Illness (IMNCI) *(4)*. By targeting hard-to-reach, vulnerable populations and supporting extension of the formal health system to the community level, iCCM increases access to life-saving interventions for malaria, pneumonia and diarrhoea, and promotes rational use of medications, home care, immunization and use of insecticide-treated bed nets (ITNs). To date, over 30 countries have implemented iCCM – mostly at the subnational level – with the support of global development partners, including substantial investments from the Global Fund to Fight AIDS, Tuberculosis and Malaria and the RMNCH Trust Fund through the malaria and Resilient and Sustainable Systems for Health (RSSH) allocations.

Lessons learned have shown that effective iCCM implementation requires district health systems and PHC facilities with the capacity to support the delivery of quality child health services within the health facility and at community level. Despite recommendations from the 2014 Accra iCCM Evidence Review Symposium (5,) many countries that initially implemented the iCCM component of the IMNCI strategy are struggling to maintain an acceptable quality of care and coverage, and large portions of the population remain underserved. Adequate planning, budgeting and resource mobilization for all iCCM components, including essential commodities, remain a major challenge in many of these countries, as does the proper inclusion of iCCM in the overall community health systems and IMNCI strategy.

WHO/CDS/GMP/MPAC/2019.13

One of the key findings of the 2016 IMNCI strategic review was the lack of prioritization of the community component alongside capacity-building of facility health workers *(6)*.

Despite these challenges, there is increased recognition of the importance of frontline health systems and the need for better alignment of resources and partners around country-led priorities for community health, building on the 10 critical principles for institutionalizing community health *(7)*.

With the aim of promoting the institutionalization of iCCM within PHC systems and comprehensive child health programming, WHO and UNICEF co-organized the Technical Consultation on "Institutionalizing Integrated Community Case Management to end preventable child deaths" from 22 to 26 July 2019 in Addis Ababa, Ethiopia. The meeting consisted of two connected parts: 1) "Institutionalizing iCCM to end preventable child deaths" and 2) "Implementation of malaria 'High burden to high impact' (HBHI) approaches and iCCM to accelerate reduction of child mortality".

The meeting brought together over 140 participants, including ministry officials representing maternal and child health and malaria programmes as well as PHC/community systems from 14 African countries with high under-5 mortality and high malaria burden. Technical experts and partners representing 17 technical and funding agencies also participated. The consultation was the first global iCCM meeting to purposely bring together representatives of national malaria control programmes (NMCPs) and representatives of maternal and child health (MCH) programmes from all participating countries, as well as representatives of agencies engaged in both malaria and MCH.

The objectives of the Technical Consultation were to:

- review recent lessons drawn from the implementation of primary health care (PHC) at the community level, particularly related to iCCM of childhood illness, in the light of new WHO guidelines on community health workers;
- develop recommendations for embedding iCCM within community health systems at the core of the PHC system;
- identify needs and gaps for sustainable financing of iCCM;
- review progress, key bottlenecks and priorities to inform national iCCM implementation plans in the context of recent learning in order to guide the malaria High Burden to High Impact response and broader child health programming and inform Global Fund applications and other resource mobilization efforts.

In preparation for the meeting, the following key documents were shared with participants: i) *WHO guideline on health policy and system support to optimize community health worker programmes*; ii) *WHO/UNICEF planning handbook for programme managers and planners: Caring for newborns and children in the community*; iii) *USAID/MCHIP indicator guide for monitoring and evaluating Integrated Community Case Management*; iv) *Journal of Global Health 2019 RAcE supplement (http://www.jogh.org/col-race.htm) (8*); v) *The Global Fund 18-country thematic review of iCCM* as part of its portfolio supporting malaria programmes and health systems strengthening.

The report of the Technical Consultation is under preparation, and the main conclusions and recommendations can be summarised as follows:

- iCCM is an effective strategy to reduce morbidity and mortality of common childhood diseases by improving equity in access and coverage of primary health care. Countries with a high burden of under-five mortality should integrate iCCM in national health policies, strategies and national health sector development plans.
- A national community health policy/strategy should be in place, containing clear, official guidelines for recruitment, job description, motivation of community health workers, as well as clear criteria for implementing iCCM with focus on hardest to reach populations.

- Adequate and sustained funding for iCCM depends upon clearly defined targeted population need and fully inclusive costing, beyond funding of "non-malaria commodities". It requires demonstrated ability of governments to coordinate diverse funding sources to support iCCM.
- To promote institutionalization and sustainability, funding agencies should coordinate iCCM funding with ministries of health and support ministries of health's iCCM implementation plan, instead of funding isolated projects in different parts of the country
- iCCM is a key component of a functional PHC system, ensuring continuum of care from community to health facilities and referral facilities, delivering quality of care at all levels, including at referral facility to manage severely ill children referred from the community.
- Attaining the highest level of quality of care at community level is dependent on competent community health workers empowered through training and mentoring, consistent supplies of tools, diagnostics and medicines, with motivation and supervision support as part of a primary health care system.
- The supply chain for iCCM should be fully integrated in the existing national supply management system, and iCCM medicines and diagnostics should be part of health facility and district level quantification, procurement and distribution.
- Supportive supervision of CHWs from the nearest health facilities is core to quality iCCM and needs to be budgeted and included in district implementation plans. District Management Teams should promote integrated supervision.
- Government led, harmonized, streamlined monitoring and evaluation systems need to include quality information and data from community activities, to guide action at local level, ensure accountability and sustained improvement of iCCM programming.
- Community engagement is key to institutionalization of iCCM. Local communities are central to planning, implementing and up-take of quality ICCM services

The second part of the consultation focused on implementation of the HBHI approaches and iCCM to accelerate reduction of child mortality in Africa. The participants worked in 13 country teams to develop country plans for optimization of iCCM to accelerate child mortality reduction in settings with high transmission, limited resources and limited access to health care services. The discussion and deliberations of each country delegations were framed according to the four HBHI response elements (or pillars): 1) Political will to reduce malaria mortality; 2) Strategic use of information, 3) Better guidance, strategies and policies; 4) Coordinated action at country level. The participants raised strong concerns for the limited financial support for procurement of non-malaria commodities of iCCM, namely amoxicillin and ORS+Zinc, compromising the effectiveness of iCCM programmes in reducing child mortality. The immediate next steps following the Technical Consultation are:

- to finalize the meeting report and recommendations for institutionalizing iCCM and scaling up iCCM as part of the HBHI approach led by WHO and the RBM Partnership to End Malaria;
- to update the 2012 UNICEF iCCM joint statement, ensuring wide dissemination, policy adoption and implementation;
- to develop an iCCM district operational manual based on best practices and lessons learnt.

References

1. United Nations Children's Fund, World Health Organization, World Bank, UN-DESA Population Division. Levels and trends in child mortality report 2018: estimates developed by the UN Inter-agency Group for Child Mortality Estimation. New York: United Nations Children's Fund; 2018 (https://childmortality.org/files_v22/download/UN%20IGME%20Child%20Mortality%20Report%202018.pdf).

2. Black RE, Levin C, Walker N, Chou D, Liu L, Temmerman M, et al. Reproductive maternal, newborn and child health: key messages from disease control priorities. Third edition. Lancet. 2016;388(10061):2811–24. doi:10.1016/S0140-6736(16)00738-8.

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4. Young M, Wolfheim C, Marsh D, Hammamy D. World Health Organization/United Nations Children's Fund joint statement on Integrated Community Case Management: an equity-focused strategy to improve access to essential treatment services for children. Am J Trop Med Hyg. 2012;87(5 Suppl):6–10. doi:10.4269/ajtmh.2012.12-0221.

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8. Sadruddin S, Pagnoni F, Baugh G. Lessons from the integrated community case management Rapid Access Expansion Program. Journal of Global Health. 2019; 9(2) doi: 10.7189/jogh.09.020101.

WHO Technical Consultation on Institutionalizing integrated community case management (iCCM) to end preventable child deaths

Dr Salim Sadruddin
Team Lead, Rapid Access Expansion (RAcE) of iCCM
22-26 July 2019, Addis Ababa, Ethiopia

Global **Malaria** Programme

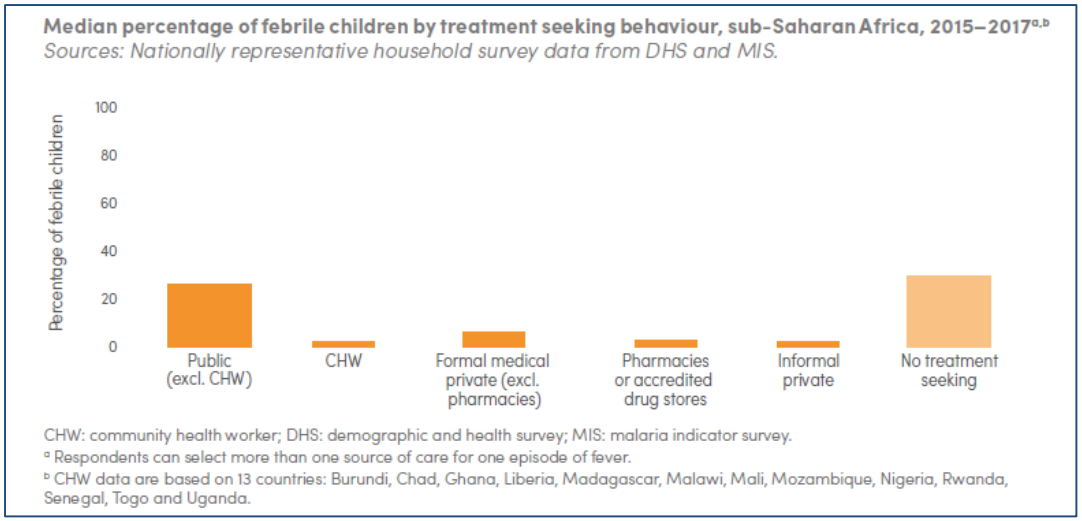
World Health Organization

Presentation Outline

- Background
  - Burden of malaria, pneumonia and diarrhea
  - Child mortality in HBHI countries in Africa
  - iCCM programs to ensure UHC in remote settings
- Meeting Objectives
- Review of recent guidance and lessons learnt
  - WHO guideline on health policy and system support to optimize CHW programmes
  - WHO/UNICEF Planning Handbook for Programme Managers and Planners: Caring for newborns and children in the community
  - Results WHO/GMP Rapid Access Expansion (RAcE) Project in 5 African countries
  - The Global Fund 18-country thematic review of iCCM to support malaria programmes and health system strengthening
- Key highlights and conclusions
- Next steps

Burden of malaria, pneumonia and diarrhoea

- Globally, 5.4 million children <5 years of age died in 2017[1], with estimated 266,000 deaths from malaria[2]
- Nearly half of U5 deaths occurred in sub-Saharan Africa
- Pneumonia, diarrhea and malaria remain the main causes of the deaths in children 2-59 months of age
- Coverage of life saving interventions, especially in sub-Saharan Africa is still low due to inaccessible or poor quality of care



1. Levels & Trends in Child Mortality. Estimates developed by the UN Inter-agency Group for Child Mortality Estimation. Report 2018. https://www.un.org/en/development/desa/population/publications/mortality/child-mortality-report-2018.asp
2. World Malaria Report, 2018 https://www.who.int/malaria/publications/world-malaria-report-2018/en/

U5 mortality in the 10 high burden African countries

Countries	Number of U-5 deaths[1]	Number and % of U-5 deaths - malaria[2]	Number and % of U-5 deaths - pneumonia[2]	Number and % of U-5 deaths - diarrhoea[2]	Number and % of U-5 deaths due to all 3 conditions[2]
Nigeria	869,879	92, 699 (10.7)	140,520 (**16.2**)	74,785 (8.6)	**308,004** (35.5)
DRC	303,618	39,001 (12.8)	39,718 (13.1)	32,902 (10.8)	111,621 (36.7)
Tanzania	110,330	6416 (5.8)	17,624 (**16**)	9,441 (8.6)	33,481 (30.4)
Niger	84,058	14,399 (17.1)	16,132 (**19.2**)	7,995 (9.5)	38,526 (**45.8**)
Mozambique	80,907	9,442 (11.7)	10,833 (13.4)	5,742 (7.2)	26,017 (32.3)
Uganda	79,481	5,992 (7.5)	14,578 (**18.3**)	6,997 (8.8)	27,567 (34.7)
Mali	78,212	20,044 (**25.6**)	11,026 (14)	7,052 (9)	38,122 (**48.6**)
Cameroon	70,028	6,678 (9.5)	10,448 (**15**)	6,884 (9.8)	24,010 (34.3)
Burkina Faso	58,525	14,641 (**25**)	7,527 (13)	4,593 (7.8)	26,761 (**45.8**)
Ghana	44,338	5,607 (12)	6,038 (13.6)	3,249 (7.3)	14,894 (33.6)

1. UN Inter-agency Group for Child Mortality Estimation (2016)
2. Estimates generated by the WHO and Maternal and Child Epidemiology Estimation Group (MCEE)

In 2016 **649,003 deaths** in under-five deaths were due to the three conditions in these 10 African countries: **47% (308,004) of deaths were** in **Nigeria** alone and **65%** (**419,625)** in **DRC and Nigeria** combined**.**

Integrated Community Case Management (iCCM)

- iCCM is a proven strategy for improving access to care, and reducing inequities and mortality from malaria, pneumonia and diarrhea[1]
- Over 30 countries have implemented iCCM with development partner support, especially Global Fund
- Many countries struggle to maintain an acceptable level of quality of care and coverage despite recommendations from the 2014 Accra iCCM Evidence Review Symposium and the 2016 Scaling up iCCM meeting in Nairobi
- Adequate planning, budgeting and resource mobilization for all iCCM components remain a major challenge, as well as proper integration of iCCM in PHC
- 2016 IMCI strategic review also showed lack of prioritization of the community component

1. Young M, Wolfheim C, Marsh DR, Hammamy D. World Health Organization/United Nations Children's Fund joint statement on integrated community case management: an equity-focused strategy to improve access to essential treatment services for children. Am J Trop Med Hyg **2012**; 87:6–10.

WHO and UNICEF Technical Consultation

Objectives of the meeting:

1. Review recent lessons drawn from the implementation of primary health care at the community level, particularly related to integrated community case management of childhood illness (iCCM), taking into account the new WHO guidelines on community health workers;
2. Develop recommendations for embedding iCCM within community health systems as the core of the PHC system;
3. Identify needs and gaps for sustainable financing of iCCM;
4. Review progress, key bottlenecks and priorities to inform national iCCM implementation plans to guide the malaria High Burden to High Impact response and broader child health programming and inform Global Fund applications and other resource mobilization efforts.

Meeting participants

The meeting brought together over 140 participants:

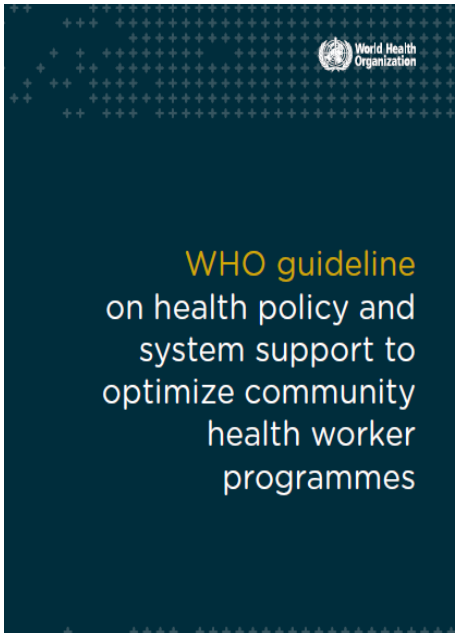
- Country delegations with WHO, UNICEF staff and Ministry officials from maternal and child health (MCH) and malaria programs (NMCP) as well as community systems from 14 African countries with high under five mortality, including high malaria burden.
- Technical experts and partners representing 17 technical and funding agencies.
- First global iCCM meeting that purposely brought together representatives from both NMCP and MCH programs of all participating countries as well representatives of agencies engaged in both malaria and MCH.

Recent guidance and lessons learnt

- WHO guideline on health policy and system support to optimize community health worker programmes
- WHO/UNICEF Planning Handbook for Programme Managers and Planners: Caring for newborns and children in the community
- Implementation research results and programme learning from WHO/GMP Rapid Access Expansion (RAcE) Programme implemented in 5 sub-Saharan African countries
- The Global Fund 18-country thematic review of iCCM as part of their portfolio supporting malaria programmes as well as health system strengthening

New WHO CHW guidelines - 2018

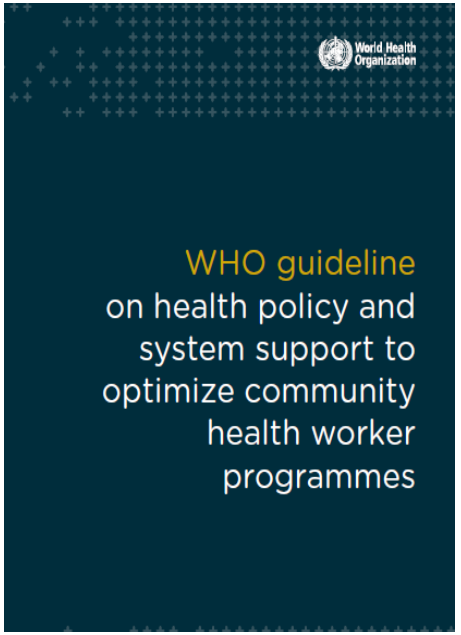
- This guideline aims to support countries in designing, implementing, evaluating and sustaining effective CHW programmes
- The policy recommendations in the guideline were developed using WHO methodology to appraise the state-of-the-art evidence, taking into account feasibility and acceptability of the recommended policy options.



- Using a health system approach, the guidelines provide recommendations in relation to CHW:
  - selection, education and certification;
  - management and supervision; and
  - integration and support by health systems and communities.

New WHO CHW guidelines - 2018

The WHO guidelines support institutionalization of iCCM with three strong recommendations:

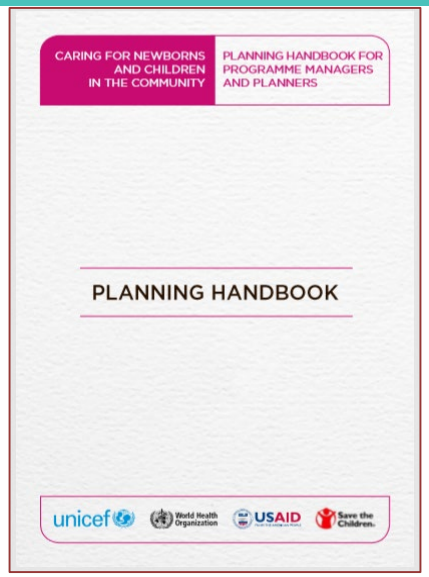


- remunerating CHWs for their work with a financial package commensurate with the job demands, complexity, number of hours, training and roles that they undertake;
- providing paid CHWs with a written agreement specifying role and responsibilities, working conditions, remuneration and workers' rights;
- adopting the following community engagement strategies in the context of CHW programs: pre-program consultation with community leaders; community participation in CHW selection; monitoring of CHWs; selection and priority setting of CHW activities; support to community-based structures; involvement of community representatives in decision-making, problem solving, planning and budgeting processes.

World Health Organization

Planning Handbook for Programme Managers

- **Inform** managers and planners about the three community-based packages, their benefits and requirements, for caring for newborns and children in the community:
  1. Caring for Newborn at Home
  2. Caring for the Child's Healthy Growth and Development
  3. Caring for the Sick Child in the Community
- Guide managers in **selecting** the best mix of community-based interventions and packages to expand or add in their country
- Guide managers through key issues and decisions in planning and implementing the packages in the context of current country activities



World Health Organization

RAcE achievement and key lessons learned

- RAcE iCCM project implemented on large scale in DRC, Malawi, Mozambique, Niger and Nigeria in 2013-2017, with over 8'500 CHWs providing care to 1.5 million children
- Major impact on child mortality in DRC, Niger and Nigeria in RAcE supported districts and provinces
- Lessons learnt:
  - iCCM relies on availability of a trained, supplied and supervised CHW in the village when a child falls ill
  - Community engagement is key for quality implementation and sustainability
  - Community and health facility quantification for medicines and diagnostics should be combined to avoid stock-outs
  - Parallel supply management system by partners are disruptive
  - Supervision from the nearest health facility contributes to quality of care, reporting, CHW motivation, connecting the CHWs to the health system
  - Functional referral to inpatient facilities is essential to manage severely ill children seeking care in the community
  - CHW data flow should be integrated in the health facility health management information system

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1. Evidence of Impact: iCCM as a strategy to save lives of children aged under five
2. Integrated community case management: Planning for sustainability in five African countries
3. Effect of community-based interventions on improving access to treatment for sick under-five children in Niger State, Nigeria
4. Improving access to appropriate case management for common childhood illnesses in hard-to-reach areas of Abia State, Nigeria
5. Community engagement and mobilization of local resources to support integrated community case management of childhood illnesses in Niger State, Nigeria
6. iCCM Data Quality: An approach to assessing iCCM reporting systems and data quality in 5 African countries
7. Data Quality Assessments stimulate improvements in Health Management Information Systems: Evidence from five African countries
8. Achievements and challenges of implementation in a mature iCCM program: Malawi Case Study
9. Home visits by community health workers for pregnant mothers and newborns: coverage plateau in Malawi
10. Barriers on the pathway to survival for children dying from treatable illnesses in Inhambane province, Mozambique
11. Testing a simplified tool and training package to improve integrated community case management in Tanganyika province, Democratic Republic of The Congo
12. A mixed-methods quasi-experimental evaluation of a mobile health application and quality of care in the integrated community case management program in Malawi
13. Clinical evaluation of the use of an mHealth intervention on quality of care provided by community health workers in southwest Niger

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Global Fund thematic review of iCCM in Africa

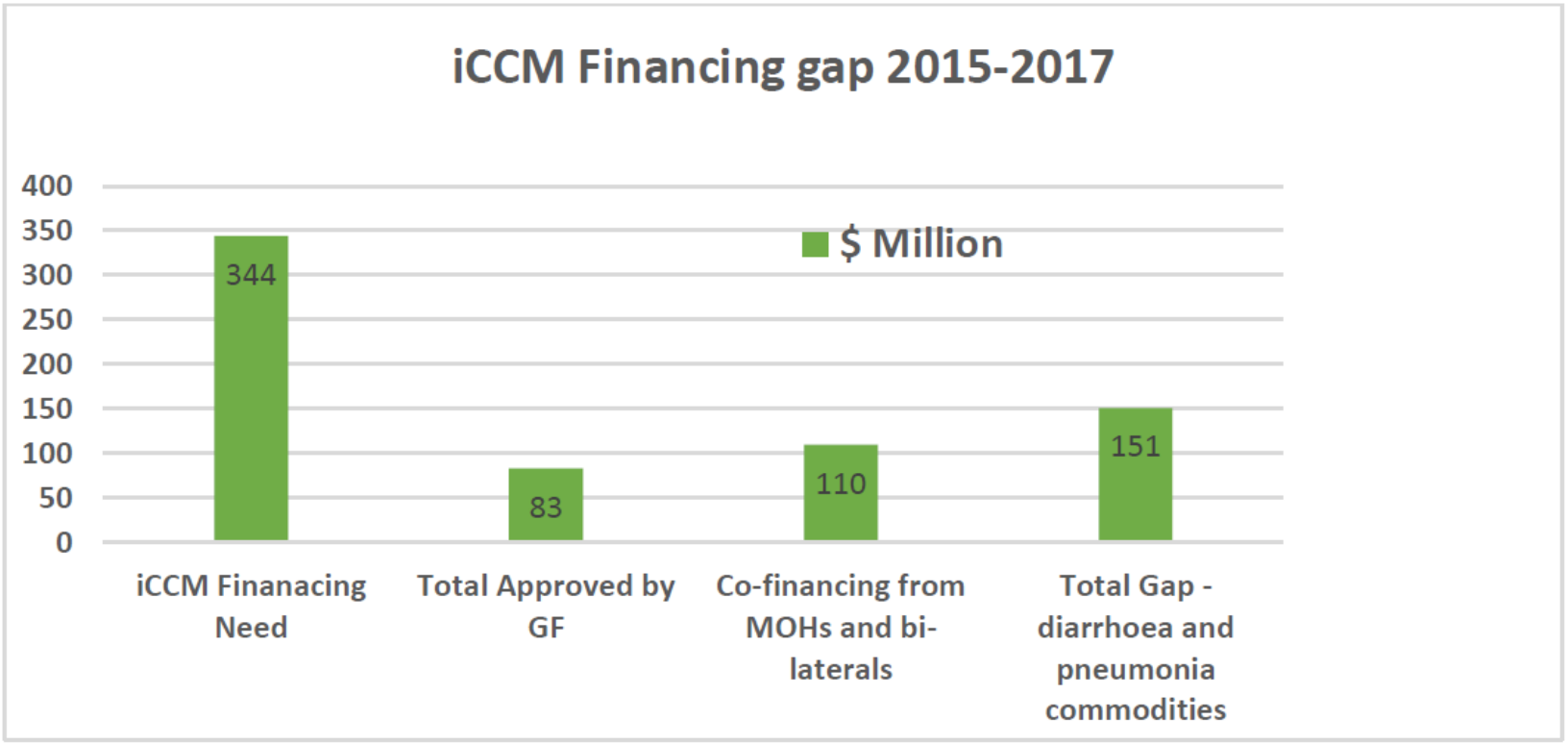
Review of experiences of iCCM implementation in 18 countries supported by the Global Fund to rollout iCCM in sub-Saharan Africa

Major challenges in scale-up

- Weaknesses in sustainable financing and integration of iCCM into national health system
- Lack of an program/institution in charge of iCCM coordination
- In few countries CHWs are institutionalized and part of the healthcare system and many countries have unpaid or volunteer CHWs
- Poor supervision due to shortage of staff at health facilities, weak links between CHWs and health facilities and limited dedicated funds
- Non-integrated iCCM supply chain, poor data on iCCM commodity consumption, and inadequate funding for pneumonia and diarrhea commodities
- Parallel community information systems supported by partners

Global Fund funding of iCCM in Africa

Malaria intervention Areas	NFM	NFM2	Grand Total
Integrated community case management (ICCM)	149,633,261	134,325,000	283,958,261
Case management	1,058,024,343	801,745,645	1,859,769,988
Total (Malaria)	**3,597,205,727**	**3,040,556,810**	**6,637,762,537**
iCCM by Case Management	14%	17%	
iCCM by total Malaria Portfolio	4%	4%	



* Nigeria, DRC, Zambia, Uganda, Ethiopia, Ghana, S. Sudan, Burkina Faso, Malawi and Cote D'Ivoire

Group work for developing recommendations to institutionalize iCCM in Primary Health Care System

Nine working groups (modified iCCM health systems benchmark matrix)

1. Coordination and policy setting
2. Costing and Financing
3. Human Resources
4. Supply Chain Management
5. Service Delivery and Referral
6. Community Engagement (communication and social mobilization)
7. Supervision
8. Quality of Care
9. Monitoring and Evaluation and Health Management Information Systems

Group work (step 1): discussion on bottlenecks / challenges pertaining to the specific system component based on country experiences

Group work (step 2): develop recommendations for institutionalizing iCCM in relation to the above health system component

Key highlights and conclusions

- Planning for iCCM should take place under the umbrella of primary health care and overall health sector development
  - A national community health policy/strategy should be in place, containing clear, official guidelines for recruitment, job description, motivation of community health workers, as well as clear criteria for implementing iCCM with focus on hardest to reach populations.
- Domestic and external funding should be targeted at system strengthening, with an inclusive focus on malaria, pneumonia and diarrhea as well as community and facility based provision of care
- iCCM should be included in the national costing exercise and the annual health sector budgeting processes, with specific budget lines
- To promote institutionalization and sustainability, donors should coordinate iCCM funding with MOH and support MOH's iCCM implementation plan, instead of funding disease or site-specific projects

Key highlights and conclusions (cont'd)

- iCCM commodities should be integral part of health facility and district level quantification
- Supportive supervision of CHWs as part of primary health care system is core to quality iCCM and needs to be budgeted and included in district implementation plans
- iCCM requires continuum of care from community-first level health facility-referral facility, having capacity to fully manage referred children
- Community engagement is key to institutionalization of iCCM: local communities are central for effective planning, implementing and up-take of quality ICCM services
- The training of CHWs should not be considered complete until demonstration of defined competencies with post training follow-up (time to be fixed as per area context) as part of training programme

iCCM in the context of HBHI response

- The high-burden malaria countries contribute an estimated 151 million cases of malaria and 266,000 under-five deaths, 10 in Africa (Burkina Faso, Cameroon, DRC, Ghana, Mali, Mozambique, Niger, Nigeria, Uganda and Tanzania) and India. Of particular concern is the increase of malaria with 3.5 million more cases in 2017 compared to previous year, among the 10 highest burden African countries
- These countries are also amongst the highest contributors to U5MR and also have some of the highest rates of pneumonia, and diarrhea deaths
- iCCM provides simplified guidance and tools for management of febrile illness that may be due to pneumonia and diarrhea in children where malaria has been excluded or those with co-morbidities
- iCCM allows identification and referral of children with severe illness with broader potential impact on child mortality

Prioritization exercise for HBHI response

- NMCP, MCH, WHO, UNICEF representatives from 10 African HBHI countries plus Angola, Chad, Ethiopia and Sierra Leone, and representatives from additional 17 technical and funding agencies working in 14 country teams
- After presentation and discussion of HBHI response, each country team discussed priority areas for scaling-up iCCM to accelerate reduction in malaria mortality based on the following 4 HBHI Pillars:
  - Pillar 1: Political will to reduce malaria deaths
  - Pillar 2: Strategic information to drive impact
  - Pillar 3: Better guidance, policies and strategies
  - Pillar 4: A coordinated national response
- Developed recommendations for identified priority areas for Ministry of Health, funding agencies and implementing partners

Next Steps

- Finalization of meeting report and recommendations for institutionalizing iCCM and HBHI response
- Updating of WHO/UNICEF 2012 Joint Statement on iCCM
- Development of iCCM District Operational Manual

VISION

IMPLEMENTING iCCM TO SAVE CHILDREN'S LIVES

AND GET OFF THE 10+1 LIST!


Many thanks
for your kind
attention