
Technical Brief

Malaria Case Management in the Private Sector

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1. Background

The private health care sector is a major provider of treatment for malaria and for non-malaria fever in malaria-endemic countries. Patients' treatment-seeking practices vary between and within countries, but overall, worldwide approximately 40% of patients with suspected malaria seek care in the private sector¹. In sub-Saharan Africa an estimated 35% of febrile children receiving medicines are treated by private providers; this proportion is likely higher among older patients². The private sector is also a dominant source of antimalarial medicines. Private providers were responsible for between 49% and 92% of all antimalarials sold or dispensed in surveys across seven sub-Saharan countries in 2012.³

“The private sector” is typically considered to include any facility, outlet or individual that provides health services, and is not managed by a government. The private sector is very diverse, ranging from private for-profit and not-for-profit health facilities and diagnostic centers, to pharmacies and drug stores, to general stores and street vendors. In some settings, care providers may be highly trained and qualified, with access to state-of-the-art diagnostic and treatment options, while other settings include providers with no formal training or qualifications.

While private providers play an important role in increasing access to case management, there are substantial concerns about quality and safety of care among some private providers, the equity impact of patients' out-of-pocket payments, and a lack of integration with the public health system. For example, in many countries there are concerns regarding: the quality of medicines sold in private outlets; poor availability of diagnosis in retail outlets and subsequent overuse of antimalarials for non-malaria fever; poor access to quality-assured artemisinin combination therapies (ACT) for those who do have malaria; continued overuse of oral artemisinin monotherapies in some settings; lack of referral links with public sector facilities; and the fact that data on malaria cases treated in the private sector are usually not available for national HMIS/surveillance. Problems with quality are not only found in the private sector – there is also a need to address many of these issues in public sector. However, private sector performance has been relatively neglected to date, despite its importance in malaria treatment provision.

To ensure effective malaria case management for all patients, as well as accurate malaria surveillance, it is recommended that countries take a “total health system” approach to addressing these challenges. This requires: 1) an understanding of the coverage and quality challenges in all provider types, and 2) strategies designed to address these challenges, while considering the relationship between sectors, and the fit with the broader health system environment. In considering the concerns mentioned, we also need to evaluate whether each element of appropriate care is better tackled as malaria-specific private sector initiatives, or with cross-cutting or “horizontal” system-wide interventions across many disease areas.

Given the variation across countries in both malaria transmission, and the nature of the private health care sector, interventions need to reflect local context. Appropriate strategies will vary depending on factors such as whether a country is in the malaria “control” or “elimination” phase, the species of malaria that are prevalent, the level of antimalarial resistance, the role of community health workers, the proportion of care provided by private providers, and the types of private providers responsible for the majority of care provided. Globally, experience in this area is growing, although in many cases there is still little evidence on the effectiveness of various interventions. Most experience is with smaller-scale pilot projects; to date, there are few large-scale or nationwide examples.

Of note, optimal approaches are likely to be somewhat different in areas where malaria transmission is higher, versus areas with low transmission. Many of the strategies proposed in this document can apply both to malaria control and elimination settings. However, the use of some strategies will depend in part, on how close a country (or regions within a country) is to eliminating

malaria. In settings that are near elimination, there is a heightened need to ensure all cases of suspected malaria are not only tested prior to treatment, so that the number of malaria cases can be accurately monitored, but also investigated and followed-up. In these settings, the role of the private sector may be limited, with an emphasis on early recognition and referral of suspected or confirmed cases. However, in countries that are in control or pre-elimination phases, the private sector may have an active role in malaria case management.

This technical brief is intended to guide countries in development of Global Fund funding requests that include engagement with private health care sector as part of a comprehensive malaria case management and surveillance strategy. The note aims to provide Country Coordinating Mechanisms (CCMs), Ministries of Health and Global Fund Country Teams with a concise review of policy options and a step-by-step guide to policy development in this area. While this brief focuses on engaging and improving care in the private sector, it is helpful to keep in mind that much of the information applies to the public sector, as well.

Objectives for engaging the private sector in malaria case management

A first step in considering whether and how to engage with the private sector around malaria is to decide *what you want to accomplish through this engagement*. That is, which aspects of private sector performance do you want to focus on? While the overall goal of engagement is to improve malaria case management and thus reduce the disease burden associated with malaria, this could be achieved through a number of different channels. We have grouped these into *seven potential objectives* for private sector engagement (while recognizing that there are many links among these objectives):

1. Ensure only good-quality antimalarial medicines are available from private providers
2. Ensure only good-quality diagnostic testing is available from private providers
3. Increase availability and affordability of quality-assured antimalarials
4. Increase availability and affordability of quality-assured diagnostic services
5. Improve case management by private providers
6. Increase consumer knowledge and awareness of appropriate treatment seeking, diagnosis, medicine choice and adherence
7. Improve malaria surveillance in the private sector

In considering your strategy, you may want to focus on one or two of these, devise a more comprehensive approach covering several or all objectives, or a systems-wide approach beyond malaria. We return to the process of determining this strategy in the step-by-step guidance in the final section of this document. First, in the following sections, we present each objective in turn, outlining strategies that can be used to achieve the objective, examples of implementation to date, the evidence base, and any practical considerations. As noted above, the appropriate private sector approach will depend on your country context, including whether your country is in the malaria control or elimination phase.

This technical brief should be read in conjunction with other documents, including the WHO Roadmap for Optimizing Rapid Diagnostic Testing in the Private Sector, expected in 2017. Links to reference documents are included in the text, and a brief bibliography is included at the end of this document for those who would like more information on specific studies and concepts.

Objective 1. Ensure only good-quality antimalarial medicines are available from private providers

Strategies

An important part of good-quality health care is access to good-quality medicines. For both public and private health care sectors, steps should be taken to ensure import, manufacture (where relevant), and distribution of good-quality antimalarials, and to prohibit antimalarials that are not effective. This is important in improving treatment effectiveness, avoiding adverse reactions, and reducing the development of antimalarial resistance as a result of sub-therapeutic dosing. In many countries, a proportion of the antimalarials on the market are either counterfeit (intentionally falsified) or of substandard quality (poorly made, or degraded), (for more information see <http://www.who.int/medicines/regulation/ssffc/en/>).

Of note, transport and storage conditions (e.g. temperature, humidity) can affect medicine quality. This consideration should be included in guidelines and monitoring strategies.

The following strategies can improve the quality of antimalarials available within countries:

- Ensure that regulatory authorities, customs inspectors and manufacturing inspectors (if relevant) have adequate power and resources to identify and remove antimalarials that are not in line with national registries and policies. Improve capacity of national medicine regulatory authorities and their linkages with other countries, and with relevant stakeholders within the country.
- Consider revising national lists of registered antimalarials to focus on products that have quality-assured status. These include products that are pre-qualified by the WHO, and/or that are on the Global Fund list of health products eligible for procurement with grant funding. Artemisinin-based oral monotherapies should be banned entirely.
- Implement post-marketing surveillance, including defining a watch-list of medicines with greatest risk of being poor quality. Conduct regular and systematic risk-based quality monitoring and control sampling among medicine distributors and retail outlets.
- Introduce nationally appropriate systems to track, trace, and authenticate medicines through the supply chain. Simple technologies are available to authenticate and verify medicines at or near the point of use. For example, in Nigeria, dispensers or consumers may use mobile phones to SMS a pack-specific code to a central number for verification. Barcode scanning technology is also becoming available <http://www.who.int/medicines/regulation/ssffc/technologies/en/>.
- If antimalarials are manufactured in country, regulate and inspect manufacturers to ensure they adhere to good manufacturing practice.
- Special packaging, for example with special logo or branding, can increase provider and consumer awareness of and recognition of quality-assured antimalarials. (See also Objectives 3 and 6.)
- Crowd out poor quality antimalarials from the market by improving the availability and affordability of quality-assured medicines (see Objective 3).

Implementation to date

Many countries have addressed antimalarial quality in their national policies, although these are not always sufficient to prevent availability of poor-quality antimalarials. In some cases, policies may be in place, but enforcement is not consistent.

In Cambodia and Myanmar (where malaria transmission is relatively low, but where antimalarial resistance is a serious problem), antimalarial quality control is offered as part of a comprehensive program managed by an NGO. The NGO provides quality-assured ACT (and RDTs; see Objective 2) through direct distribution to retail providers.

In Ghana and Nigeria, representatives from national regulatory agencies screen medicines at wholesale and/or retail outlets; providers of counterfeit medicines are penalized. In Cambodia, regulators visit outlets to conduct post-market surveillance, and are legally empowered to close outlets that stock poor-quality medicines.

Examples of special packaging to increase consumer recognition include: quality-assured ACTs subsidized through the Affordable Medicines Facility – malaria (AMFm) were labeled with the “Green leaf” logo; this practice is on-going in countries implementing the Private Sector Co-payment Mechanism for ACTs supported by the Global Fund. The “Supa Arte” ACT in Myanmar is labeled with a lotus plant.

Evidence to date

There is a growing amount of information on the quality of antimalarials on the global market (for example <http://www.wwarn.org/aqsurveyor>), although we do not know precisely how prevalent poor-quality medicines are as this can vary considerably geographically and over time.

In many areas, substandard antimalarials (i.e. poorly made or degraded) are more common than counterfeits (intentionally falsified). For example, a research consortium collected and analyzed over 10,000 artemisinin-based medicines from six malaria endemic countries: Cambodia, Equatorial Guinea, Ghana, Nigeria, Rwanda and Tanzania. Laboratory analyses of these medicines showed that falsified antimalarials were found in just two of the countries; but substandard ACTs were present in all six countries, and artemisinin-based monotherapy tablets were also still available in some places.⁴

To date, there is not much evidence on how to improve and ensure the quality of medicines available in countries. However, strategies that support the capacity of medicine regulatory authorities, and improve access to good-quality pre-qualified medicines are likely to be key. Ensuring procurement of quality-assured antimalarials at the point of import (or manufacture) is an important step. Private distribution chains and pharmacies may be required to comply with Good Pharmacy Practice and Good Distribution Practice. After medicines are distributed, facilities that sell medicines (clinics, pharmacies, drug shops) should be inspected regularly to ensure sale of only registered and pre-qualified products. ACTwatch data (www.actwatch.info) show that regulatory and screening efforts have had a positive effect.

For example, in Myanmar, the market share of oral artemisinin monotherapies (which drive resistance) dropped significantly, and was overtaken by recommended ACT.

The Minilab can detect falsified antimalarials⁵ but it is not likely to be accurate for detecting substandard antimalarials. Some new portable devices, e.g. based on Raman spectroscopy, are promising⁶ but none has been fully and independently evaluated; and again, they are not likely to be accurate for detecting substandard antimalarials that drive drug resistance.⁷ Increasing data sharing between and within countries is key, and all poor quality antimalarials should be reported both to the national medicine regulatory authority and to the WHO Medical Product Alerts system (see www.who.int/medicines/publications/drugalerts/en/).

Practical considerations

Medicine regulating and enforcement authorities are often under-resourced. Sufficient allocation of funds, human resources and laboratory capacity are needed to enable transparent and consistent regulation and enforcement. Within a given country, some responsibilities for this work likely lie outside the malaria-specific community, countries may consider allocating resources for strategies to regulate medicine quality in general, as well as malaria-specific activities. The proportion of poor-quality antimalarials in a country can vary over time, so continuous or periodic monitoring is more effective than one-time surveys.

Objective 2. Ensure only good-quality diagnostic testing is available from private providers

Strategies

It is now well recognized that accurate diagnosis is a critical part of malaria case management, as well as being important for malaria monitoring and control. The WHO, and most country guidelines, emphasize that parasitological diagnosis (i.e. blood testing) should be done before antimalarial treatment is given. For both public and private health care sectors, steps should be taken to ensure import (or manufacture) of quality-assured diagnostic products. Some of the strategies for diagnostics are similar to those in Objective 1 for medicines, while others are specific to diagnostics.

As for medicines, transport and storage conditions (e.g. temperature, humidity) can affect the quality of diagnostic testing products. This consideration should be included in guidelines and monitoring strategies.

- If necessary, update national lists of registered diagnostic devices to include only quality-assured (QA) products. From 2008, the WHO led the Malaria RDT Evaluation Program: every year, malaria RDTs on the global market are tested against a standard panel of malaria parasites, and the results are published (see 2015-16 results at <http://www.who.int/malaria/publications/atoz/9789241510035/en/>). As of 2016, the WHO is expanding this program to include Prequalification of Malaria RDTs. Currently, 12 malaria RDTs from four manufacturers are WHO prequalified (Table 1 at <http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/>). Countries should review their registered lists of malaria RDTs and consider harmonizing them with the WHO recommendations.
- Require that once lots of RDTs reach the port of entry, and before distribution, RDTs from each lot are sent for quality control testing. This low-cost, quick service is performed at independent laboratories monitored by the WHO. Details of the lot testing program are at <http://www.who.int/malaria/publications/atoz/procedures-rdt-testing/en/>.
- Special packaging, for example with special logo or branding, can increase provider and consumer awareness of and recognition of quality-assured diagnostic products. (See also Objectives 1, 4 and 6.) In addition, like the track, trace, and authenticate technologies described for medicines (see Objective 1), similar approaches may be used in the diagnostics supply chain.
- Ensure that regulatory authorities, custom inspectors and manufacturing inspectors (if relevant) have adequate power and resources to identify and remove diagnostic devices and materials that are not in line with national registries and policies.
- Implement post-marketing surveillance to monitor the quality of diagnostic products stocked by distributors and retail providers. Surveillance typically benefits from a multi-sectoral approach, including regulatory authorities and representatives from diagnostics services.
- In the near future, countries may consider implementing positive control wells (PCWs) in private as well as public health sectors. PCWs are designed for use by health workers and inspectors to confirm whether stocks of RDTs are performing accurately (<http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/positive-control-wells/en/>).

Implementation to date

The WHO product and lot testing programs have been in place since 2008 and are widely used by governments and organizations that procure RDTs for use in the public sector across Africa and Asia. The programs were also used in UNITAID pilot projects that implemented RDTs in private health care outlets in five countries (Kenya, Madagascar, Nigeria, Tanzania and Uganda). The food and drug regulatory authority in Cambodia manages regulation and lot testing of diagnostic products. Cambodia has also established a relationship with an NGO that visits facilities to sample and test diagnostics in stock.

Special packaging, or technology to authenticate diagnostic products, is used in some countries. In Cambodia, logo stickers are applied to quality-assured diagnostics after importation (rather than

requesting special packaging from manufacturers, or re-packaging in country). As for medicines (Objective 1), at least one country is also trialing the use of pack-specific codes, checked by end users with a mobile phone SMS system, for malaria diagnostic products.

Evidence to date

In the public sector, over the past few years the WHO RDT product and lot testing programs have had a beneficial effect in shifting the market toward quality-assured products.⁸ Similar success may be achievable in the private sector.

There is wide agreement that post-marketing surveillance of diagnostic products should be done; but to date there are few reports and little evidence from implementation. Results from the UNITAID projects mentioned above will be made public soon

(www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/private-sector/en/;

<http://www.unitaid.eu/en/creating-a-private-sector-market-for-quality-assured-rdts-in-malaria-endemic-countries>). These results also form the basis of the WHO Roadmap for Optimizing Rapid Diagnostic Testing in the Private Sector, expected in 2017.

Descriptions and preliminary results from some pilot projects, including some UNITAID projects, are available (see links to PowerPoint presentations <http://www.actconsortium.org/pages/private-health-care-sector.html>).

PCWs are currently being evaluated among private health care providers in Tanzania; results will be publicized in 2017.

Practical considerations

Some countries have encountered challenges with Objective 2 because of slow or inflexible regulatory processes, and/or because the country has multiple regulators with different agendas and overlapping authority related to diagnostics. Identifying the relevant authorities and policies, identifying potential bottlenecks, and bringing all stakeholders on board early on may help to overcome these challenges.

Objective 3. Increase availability and affordability of quality-assured antimalarial medicines where appropriate

Strategies

Ensuring that all antimalarials are of good quality (Objective 1) is an important first step, but that alone does not guarantee that the recommended first line ACTs will reach patients in need. Other activities are typically needed to ensure appropriate distribution at affordable prices (Objective 3), to encourage their appropriate use (Objective 5) and to promote consumer demand (Objective 6).

- A commonly recommended way to increase availability and affordability of ACTs is by subsidizing them. Subsidies use government or donor funds to pay part of the cost of bulk procurement of quality-assured ACTs (with bulk procurement itself also reducing prices), so that in-country wholesalers and retailers can then purchase the ACTs at a cost below market value. In a successful subsidy program, the lower cost to providers is passed on to patients, improving affordability and availability and thereby promoting use of quality-assured ACTs over non-recommended treatments. This can also help to “crowd out” and reduce consumer demand for non-recommended treatments (e.g. those that are not efficacious, or that drive resistance), and those that are poor quality (see Objective 1).

Subsidy programs must be supported by other interventions within each country to achieve their best impact. The following interventions can be used with, or without, subsidized antimalarials:

- “Social marketing” of antimalarials uses marketing techniques to encourage consumer demand for recommended products. For example, this can be done with specially designed packaging for recommended ACTs, logos to designate quality assurance (see Objective 1), and providing information and training about recommended quality-assured antimalarials to private providers and consumers (see Objectives 5 and 6). Ensure key messages are harmonized with those already used to support public sector treatment seeking.
- Setting recommended retail prices (RRP) for recommended ACTs and making these known to providers and patients, for example by printing the RRP directly on the ACT package, applying stickers with logos and RRP information, and/or referencing the RRP in communication activities. RRP can help to ensure that prices are affordable, and that access is equitable, for the targeted patient populations.

Implementation to date

Cambodia was the first country to subsidize ACTs in the private sector, launching a nationwide social marketing project in 2002 to promote subsidized co-blistered ACTs with the brand name Malarine. Other experimental and pilot ACT subsidy schemes involved limited geographical areas and/or small number of providers (e.g. in East Africa), while Madagascar also implemented a nationwide pediatric subsidy program.

These initiatives were followed by the AMFm, the largest ACT subsidy initiative to date. AMFm involved price reductions from the manufacturers, subsidies “at the factory gate” at the top of global supply chain, and supporting interventions in each country. AMFm was implemented nationwide in seven countries 2010-2013 and has now been integrated into the Global Fund grant management and financial process (see separate information note on the Private Sector co-payment mechanism http://www.theglobalfund.org/documents/core/infonotes/Core_AMFm_InfoNote_en/).

In some countries, the national government (or an organization acting on behalf of the national government, e.g. PSI or CHAI) has negotiated an advantageous bulk price for quality-assured antimalarials directly with the manufacturer. The antimalarials are procured and imported, and distributors and private providers then purchase antimalarial supplies and sell them at a small profit.

In Myanmar, the Artemisinin Monotherapy Replacement Project (AMTR) attempted to replace oral artemisinin monotherapies (oAMT) with ACTs. The AMTR project introduced a subsidized ACT (Supa Arte, with a lotus logo) along with a ban on oAMT, plus supporting interventions directed at providers and consumers.

Along the same lines, a modified subsidy approach has recently begun in the Democratic Republic of Congo (called DEFEAT). An NGO is managing a time-limited subsidy for quality-assured ACTs; the value of the subsidy is highest in the first few years, and then will reduce over time. This “market development” approach will test the idea that quality-assured ACTs may not require a permanent subsidy. Supporting interventions include the use of the Green Leaf logo on all subsidized ACT packaging; medical detailing (paid for by the manufacturers or their importers) to promote the products; and communication campaigns for the consumer population about the Green Leaf logo.

Evidence to date

Most (though not all) subsidy programs have led to greater ACT availability and market share in both urban and rural areas, and to lower prices.

- The AMFm countries which achieved the largest increase in quality-assured ACT market share had stronger implementation of supporting interventions (e.g. IEC campaigns);

countries with the weakest results had antimalarial markets dominated by small retail outlets that were not officially permitted to stock antimalarials.

- Some subsidy programs have set an RRP that providers should charge for ACTs. Evidence on RRP is mixed; providers adhered to RRP in four studies of sub-national subsidy programs, but in some national programs adherence was lower.⁹ Overall, adherence to RRP may be encouraged by strong communication campaigns and adequate product supply.
- ACT subsidy programs have also contributed to declines in oAMT market share in countries where it was substantial at baseline, although subsidy programs alone have not succeeded in completely removing oAMT from the market.
- For example, Cambodia's national policy states that private outlets may only test and treat for malaria if the individual provider is licensed and registered (see definitions in the "Cross-cutting strategies" section later in this document). Officers from the national food and drug authority visit private outlets, review documents and qualifications, and check commodities in stock. This has shown some success in "crowding out" non-recommended antimalarials, specifically oAMT.^{10, 11}

Practical considerations

The overall approach to Objective 3 should achieve a balance between patient access and regulatory control. Careful consideration must be given to specifying which antimalarial medicines can be sold, which providers are allowed to sell them, whether they can be available over-the-counter or by prescription only, and whether they should be provided with diagnostics.

Some countries choose to promote different types of antimalarials, or different products, in their private versus public sectors. Approaches include: 1) use of multiple first-line therapies within a country as way to delay resistance; 2) use of the same first-line therapy for all sectors, but with different packaging to enable easy identification of "leakage" from public to private sector outlets. In settings where malaria elimination is underway, it may be best to restrict the range of outlets that are allowed to provide antimalarials. For example, antimalarials may be restricted to higher-level providers with strong links to the public sector. (Other supportive interventions such as provider and consumer education will be critical if restriction is a change from previous practices.) For example, in areas of Cambodia near to elimination, policy states that private providers are not allowed to sell antimalarials; they are allowed to do testing and are supposed to refer patients for treatment. It is not yet clear how effective this ban is in practice.

In many malaria elimination settings, non-falciparum malaria, in particular *P. vivax*, is the predominant species (<http://www.who.int/malaria/publications/atoz/9789241509244/en/>). Complete treatment of *P. vivax* requires an additional drug active against hypnozoites, the liver stage of the parasite that cause relapses; the only such drug currently available is primaquine, which requires 14 days treatment and testing for G6PD deficiency prior to treatment. Realistically, ensuring good quality case management of *P. vivax* in the private sector may currently be feasible only in higher-level facilities.

Objective 4. Increase availability and affordability of quality-assured diagnostic services where appropriate

Strategies

Ensuring the quality of diagnostic products in country (Objective 2) is an important first step, but that alone does not guarantee that they will reach patients in need in the private sector. As for antimalarial medicines (Objective 3), other activities are typically needed to ensure appropriate provision at affordable prices (Objective 4), to encourage their appropriate use (Objective 5) and to promote consumer demand (Objective 6).

In some settings, microscopy services may already be in place, for example in higher-level private facilities and diagnostic laboratories. For these providers, the focus should be on promoting good quality.

Malaria RDTs are widely seen as a way to increase availability and affordability of diagnostics in both health facilities and medicine retailers. Some of the strategies suggested for improving availability and affordability of antimalarial medicines (Objective 3) can also be applied to diagnostics, along with some strategies that are specific to RDTs:

- Ensure national policies allow use of RDTs by private health providers. Guidelines should clarify where RDTs may be used (e.g. in higher-level facilities and laboratories, in pharmacies, in drug shops, etc.). It may be appropriate to make provision of appropriate diagnostics a condition for planned or existing accreditation programs (see “Cross-cutting strategies”).
- Reduce RDT retail prices through bulk procurement and where necessary product subsidies. Combine this with supporting interventions such as social marketing, RRPs, training, identifying and expanding distribution channels, communication activities, etc. These strategies can be brought together under an holistic “market development approach” that aims to create and stimulate a market for affordable RDTs.

Implementation to date

Diagnostic services (microscopy and RDTs) are available in higher-level private facilities in some countries. Quality-assured diagnostic services have not been implemented at scale in the private retail sector, except in Cambodia, where subsidized RDTs are available from private providers participating in the Public-Private Mix program (including registered and licensed providers, primarily for-profit clinics and some pharmacies, that offer both malaria testing and treatment services). Recommended RDTs are the same product as the one used in the public sector, labeled for sale through Public-Private Mix providers. The Public-Private Mix program is run by the National Malaria Control Program (NMCP) with support through implementing NGO partners.

A number of small-scale pilot studies have been conducted of RDT introduction among private providers in several countries (including the UNITAID projects mentioned earlier in Kenya, Madagascar, Nigeria, Tanzania and Uganda, as well as other projects in Angola, Ghana, Liberia, Myanmar and Zambia). For example, a UNITAID pilot in Kenya took a market development approach including negotiated buying price and demand generation. In other countries, the pilots used upstream subsidies at the manufacturer level.

In Ghana, ACT and RDT prices are set by the free market. RDTs are subsidized by the NMCP, and a retail price was agreed but is not legally enforced. The pharmacies and chemists self-regulate through professional associations with regular meetings.

In Myanmar, an RDT subsidy plus various provider incentives has been deployed. Providers are re-supplied with RDTs (at a low cost) in exchange for used RDTs; in some cases they are given a free RDT kit after using a certain volume of RDTs; and providers are visited regularly for support supervision and education. In Cambodia, an incentive program is also in place, whereby providers are given a pen or umbrella (for example) after returning a certain volume of used RDTs. Note: for programs like these, the incentive must be linked to a commodity that providers purchase (so that the commodity is not used or wasted just to obtain the incentive).

Evidence to date

Where RDTs have been introduced in the private retail sector, uptake varies widely (reports from 8% to 100%). Subsidies have been used in most implementation projects and studies; exceptions to this include a pilot in Kenya, and a study in Tanzania where it was found that subsidies did not

affect RDT uptake. Based on this finding, Tanzanian authorities decided to maintain a negotiated low RDT cost at the manufacturer level, rather than use a subsidy mechanism.

In Uganda, a small pilot project showed good acceptance and use of RDTs in private retail outlets. This project was accompanied by strong and visible support from the Ministry of Health and use of standard signs/logos on drug shops to enhance community awareness and recognition.^{12, 13} As mentioned under Objective 2, results from the UNITAID projects will be made public soon (www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/private-sector/en/; <http://www.unitaid.eu/en/creating-a-private-sector-market-for-quality-assured-rdts-in-malaria-endemic-countries>). These results support the forthcoming WHO Roadmap. Descriptions and preliminary results from some pilot projects, including some UNITAID projects, are available (see links to PowerPoint presentations <http://www.actconsortium.org/pages/private-health-care-sector.html>).

Practical considerations

RDTs for the private sector, as for the public sector, must be implemented as part of a comprehensive service and not just as a commodity (see Objective 5). Most of the evidence available to date is from smaller-scale pilots and studies; larger scale-up will likely require considerable investment, and careful planning reflecting local contexts. When introducing diagnostics into the private sector, it will likely be efficient to use, as much as possible, existing distribution channels for medical supplies. Similarly, adapting informational or publicity materials that have already been developed for use in the public sector can help to harmonize messages across target populations.

In most settings, if ACTs are subsidized, diagnostics should also be subsidized, in order to encourage testing before treatment. Calculations should consider the final prices of both diagnostic services and ACTs to clients/patients, ensuring that diagnosis is cheaper than treatment (or at least that they are of equal price). Likewise, experience in some UNITAID projects has found that if each provider along the supply chain is able to keep a profit margin, they are more motivated to continue providing quality-assured diagnostics.

RRPs for ACTs and diagnostics should be set carefully to incentivize both providers and consumers. The optimal prices are likely to depend on local circumstances including malaria prevalence. It will be helpful to conduct market testing within countries to determine optimal pricing.

In malaria elimination settings, the approach to diagnostics in the private sector depends on factors including: the level of awareness of malaria in the population; the current role of private providers in fever case management; the current availability and quality of diagnostic services; and the linkages between the private and public sector. Encouraging availability of diagnostic services at some private providers may be appropriate. However, as an area draws closer to elimination, restrictions should be placed on which providers are allowed to offer diagnostic services, in order to ensure appropriate management and reporting.

Objective 5. Improve case management by private providers

Strategies

To improve health care, good-quality health products – medicines and diagnostics – must be supplied as part of a comprehensive package, with thoughtful interventions to ensure they are used correctly. In most cases, effective implementation will require significant attention to training and support supervision, together with on-going communication efforts directed to both providers and consumers (Objective 6).

- Countries may wish to consider whether private providers should manage, or refer, small children, pregnant women, severe malaria cases, and other vulnerable populations.

- Use a variety of channels to raise private providers' awareness of new interventions and guidelines: for example, via professional associations, training sessions, and outlet-to-outlet visits by health promoters. (Providers are also likely to be exposed to general community information campaigns as in Objective 6.)
- Train private providers on symptoms, recommended diagnostic procedures, recommended antimalarials and dosing, and the importance of patient adherence. Clear guidelines on management of malaria-negative cases are critical – this remains a challenge across all sectors but is a key part of successful RDT implementation.
- Develop guidance and train private providers in when and how to appropriately refer patients (e.g. with complicated or severe symptoms) to other health care levels or sectors. Guidance should consider how to optimize communication between referring providers and receiving providers. In general, referral and information sharing between private and public providers is a challenge in many countries. Efforts should be made to strengthen coordination across public and private sectors on national and sub-national levels.
- It can be efficient to use or adapt materials (for example, training manuals, job aids) that are already available for public sector staff or community health workers. Using similar materials across health care sectors also helps to harmonize messages across target populations. Longer duration of training correlates with improved outcomes in many settings, but private providers may be reluctant to spend time away from the work site due to loss of income; on-the-job training, and/or on-site support supervision soon after training, may help to balance this concern. Training may be provided free, or at a cost to the provider, depending on the context. Completion of approved training may be required as part of an accreditation program for private providers.
- Packaging of medicines and diagnostics with recognizable logos has been mentioned in Objectives 1-4 as a way of communicating quality assurance. In addition, packaging may include pictorial dosing or use instructions, stickers with simple messages to encourage adherence, or other messages.
- Where microscopy is already performed, consider monitoring the quality, and accrediting microscopy services. (RDT quality assurance is discussed in previous sections.)
- Blood safety is a major concern when introducing testing in new settings. There is a clear danger of spreading hepatitis viruses, HIV, and other infections if providers do not use appropriate techniques and safe waste disposal. It is critical to establish a system for safe disposal of sharps (e.g. single-use lancets used to obtain finger prick blood) and other medical waste, and training on blood safety.
- After training, ensure follow-up and support supervision. Members of professional associations may be enlisted to visit outlets for this purpose.
- Mobile phone-based interventions may be used to send key messages to providers (e.g. diagnostic algorithms, dosing, advice) and/or patients (e.g. treatment-seeking, adherence to recommended treatment).
- Consider what kind of record-keeping and reporting is appropriate for private providers, to allow monitoring and evaluation of care, and to feed into the country's malaria surveillance system (see also Objective 7).

Implementation to date

Diagnostic services (microscopy and RDTs) are available in higher-level private facilities in some countries. Microscopy and RDTs have not been implemented at scale in lower-level private facilities, except in Cambodia, where socially marketed, subsidized RDTs are available at many smaller private outlets (see details, plus other pilot project summaries, under Objective 4). As in the public sector, age- or weight-specific blister packaging has been used in private sector settings with subsidized or socially marketed antimalarials. Phone-based SMS messages have been piloted to remind providers of treatment guidelines and advice for patients (Tanzania) or to encourage patients to adhere to treatment (Ghana, Nigeria).

Training on malaria transmission, symptoms, treatment guidelines and communication with patients has been conducted in many private retail contexts. Some programs have used on-the-job training and support supervision during visits to individual outlets. In the Nigeria UNITAID study, members of the national private health providers' professional association conducted support supervision visits. In the Kenya UNITAID project, monitoring and reporting allowed supervision to prioritize outlets with a high volume of patients, and outlets that were not performing well. In the Cambodia Public-Private Mix model (mentioned in Objective 4), training for eligible providers is offered free of charge. This is a 1 to 1.5 day training on recognition of danger signs, malaria symptoms, appropriate case management, reporting and referral; plus stock management, financial guidance and recommended retail price). Most providers are trained health practitioners, who offer other health services as well (e.g. maternal and child health, reproductive health, general health care). The Public-Private Mix model also includes support supervision visits and quality assurance assessments.

Evidence to date

Much of the available evidence on Objective 5 overlaps with that already summarized under Objective 4, including the forthcoming WHO Roadmap and UNITAID project results. In addition, a systematic review that will be published soon (Visser, et al) identified 12 studies that introduced malaria RDTs in private retail medicine outlets, mostly in sub-Saharan Africa. All were small-scale, controlled pilots of RDT introduction in drug shops or pharmacies. Outcomes varied widely across studies. In particular, provision of ACT for test-positive patients varied from 30-99%; and 2-46% of test-negatives were treated with an antimalarial. Longer provider trainings, frequent supervision, and lower RDT retail prices all appeared to have a beneficial effect on RDT uptake and provider adherence to test results.

DHIS2, an open-source web-based information system (www.dhis2.org), is used in Cambodia to track malaria caseload data, commodity sales, and quality of care among private providers. During monitoring visits, a questionnaire is administered to private providers, assessing their malaria knowledge, fever case management skills, reporting, environmental cleanliness and overall quality of care. The questionnaire generates a score; this score enables supervisors to prioritize visiting providers who have lower score and higher caseloads. This system also allows the national program and implementing partners to track provider performance over time. Early unpublished data indicates a positive effect on provider quality of care.

Practical considerations

As mentioned under Objective 4, implementation of RDTs must be viewed as the introduction of a comprehensive service, and not only as provision of commodities. The current evidence is mostly from smaller pilot studies; careful planning and considerable investment will likely be required for successful implementation at national scale.

Guidance for management of malaria-negative cases is an important part of successful RDT implementation, but remains a challenge across all sectors. Countries may wish to harmonize guidelines for both public and private providers, for clarity and consistency.

High staff turnover at private facilities may prove a challenge in some areas. Training and monitoring approaches should consider how to ensure a sustained level of appropriately trained staff in private outlets.

Countries may also wish to consider a trial of the integrated community case management (iCCM) intervention in small or remote private outlets, especially in areas where other health care is not readily available.¹⁴ A pilot study in Uganda implemented iCCM, including malaria RDTs, in registered drug shops. In the study area, iCCM was found to improve access and appropriateness of care for children seen at the drug shops.¹⁵

In **malaria elimination** settings, as described under other Objectives, it may be wise to restrict case management to higher-level private facilities and to providers who have strong linkages to the public sector. Ensuring that patients complete treatment is critical and may include Directly Observed Therapy (DOT), plus follow-up weeks after treatment to ensure complete cure. For example, this approach is used in some areas of Cambodia, where village malaria workers are paid an incentive to perform DOT.

Objective 6. Increase consumer awareness of the importance of appropriate treatment seeking, diagnosis, medicine choice and adherence

Strategies

In addition to Objectives 1-5, improving health care services also requires effective communication to consumers (patients and caregivers). Communication can help increase knowledge about the transmission, prevention, diagnosis and treatment of malaria. However, knowledge alone is not enough; communication also needs to motivate individuals to take action – for example, getting tested, and completing the full dose of medicines. Social and Behavior Change Communication (SBCC) aims to influence the target audience to adopt desired behaviors, and to change or create norms around those behaviors.

The Roll Back Malaria (RBM) Partnership provides helpful guidance and toolkits for SBCC in “The Strategic Framework for Malaria Communication at the Country Level, 2012-2017), available at www.rollbackmalaria.org/files/files/globaladvocacy/docs/BCCstrategicFramework.pdf

An integrated SBCC strategy to enhance interventions for malaria case management in the private health care sector may include:

- Logos and branding of recommended antimalarials and diagnostics (see Objectives 1-4).
- Signs, logos and/or branding of private outlets that meet approved standards for provision of quality services (for example, if an accreditation scheme is in place; see “Cross-cutting” section).
- Generating demand among consumers for the need to test before treating, and for good-quality products and services: for example, through door-to-door household visits by health promoters (volunteer or paid), community sensitization meetings, short films or dramatizations shown in public spaces, radio and/or television spots, signs or billboards, messages given to children in school, and social media or SMS platforms.

Implementation to date

The AMFm (see Objective 3) was implemented at national scale in eight African countries, and included communication campaigns to promote availability of quality assured ACTs in the private sector, and appropriate ACT use.

At least 11 projects in Africa and Southeast Asia have introduced malaria RDTs in private outlets alongside communication activities, like those listed above, to generate consumer demand. It is not clear to what extent communication, compared with other factors, contributed to the success of each program.

SBCC activities were included in UNITAID projects that introduced RDTs in private outlets in five African countries. For example, in Ghana, a short film was produced showing RDT use in chemist shops, and screened to the community in open areas. In Uganda, SBCC targeting the community focused on identification of symptoms and promotion of testing. In Tanzania a radio campaign broadcast generic messages (test and treat) as well as branded messages (for diagnostic tests at private outlets), as well as training for the private sector pharmacies.

Evidence to date

Data from over 19,500 outlets in AMFm areas indicated that longer-duration communication campaigns (i.e. running for more than five months) were associated with higher levels of AMFm awareness and knowledge among private providers. This in turn was associated with a greater increase in market share of quality-assured ACTs.

Many programs that introduce ACTs and RDTs in the private sector have included SBCC activities. While SBCC programs have likely contributed to the success of case management interventions in various health care settings, currently there is not much specific evidence from private sector settings.

Practical considerations

SBCC projects are most effective when a combination of strategies is used, for example, communication through mass media *and* interpersonal contacts. The most successful SBCC interventions are evidenced-based and tailored for particular contexts and populations. A step-by-step guide for SBCC is available at <http://healthcommcapacity.org/i-kits-sbccimplementationkits/>. The choice and design of communication strategies should be based on consideration of the target audience; for example, community sensitization meetings may be most appropriate for some populations, while radio or television spots may be more effective for others. Pre-testing messages and strategies, and obtaining feedback from target audiences, can help to tailor communication before wider use.

The timing of SBCC activities is important; they should coincide with other elements of the intervention. For example, if a communication campaign is conducted months before an intervention is rolled out, most of the target population will have forgotten the information communicated by the time it is needed. SBCC activities conducted over at least several months are likely to be more effective than short-term or one-off publicity events.

In malaria elimination settings, messages may emphasize: raising awareness about malaria and who is at risk; encouraging early treatment-seeking, and indicating (e.g. with signs or logos) where treatment should be sought; promoting test-and-treat in malaria hotspots (e.g. as done in Zanzibar); explaining why testing may be needed for asymptomatic people (Cambodia), or why prophylaxis and bed nets are important for travelers (Swaziland).

Objective 7. Improve malaria surveillance in the private sector

Strategies

Strengthening malaria surveillance is a central pillar of the WHO Global Technical Strategy for Malaria 2016–2030 (http://www.who.int/malaria/areas/global_technical_strategy/en/). Accurate and timely surveillance data is a basic requirement to monitor progress in malaria control, identify gaps in program coverage, direct resources where they are needed most, and in areas of low transmission to detect outbreaks and foci of ongoing transmission. Although surveillance is valuable in all transmission settings, the aims and methods of surveillance change as transmission declines, with a shift from reporting aggregate case data to identifying and investigating every individual case.

In most countries, there is still room for improvement in public sector reporting; and there are often no data at all from the private sector. In countries where a large proportion of malaria cases are managed in the private sector, this constitutes a major data gap.

- Accurate data from private providers will depend on the availability and use of appropriate diagnostic methods (Objectives 2, 4 and 5).
- Mobile technology¹⁶ can improve the completeness and timeliness of routine reporting in health management information systems (HMIS), although to date there is little experience

with large-scale implementation. Innovations in mobile technology in HMIS, often piloted first in public sector, may also be considered for the private sector. However, different motivations for reporting and other factors may require a slightly different approach for implementation in the private sector.

- In elimination settings, making malaria a notifiable disease can encourage reporting.

Implementation to date

Experience of data collection from private sector providers is limited. Larger providers (private hospitals, clinics and laboratories) that are regulated by government may report routinely as part of national HMIS, but drug shops often do not. Franchising and accreditation programs (see “Cross-cutting strategies” section) may include reporting requirements, but such projects often developed unique reporting structures, rather than integrating into existing national systems. A large NGO-run project uses mobile phones and tablets in private clinics and drug shops in some countries to collect data onto a DHIS2 platform (www.dhis2.org, an open-source web-based information system also mentioned in Objective 5). Use of the same platform that is already used in national surveillance systems facilitates data sharing at national level. SMS-based reporting also enables collection of geo-located data and relatively precise mapping of cases in time, which is especially valuable in low transmission and elimination settings.¹⁷

In Ghana, private health facilities such as hospitals and clinics are supervised by the district health directorate. The private facilities are required to report their case data as part of the district’s data in DHIS2, but private sector reporting is typically low. In a drive to increase private sector reporting, the NMCP recently sent data managers to the field to provide support on data issues to both public and private facilities.¹⁸

Surveillance is a key intervention in countries working toward **malaria elimination**, where malaria should be a notifiable disease. Surveillance of malaria cases managed in the private sector is now an integral part of the malaria elimination action plan in a number of countries.¹⁹ For example, the Coconut surveillance system in Zanzibar was introduced initially in public facilities and has now been extended to all private clinics.²⁰ In Cambodia, an NGO provides Malaria Case Surveillance Application (a smartphone app) for case reporting and referral. Both systems allow real-time integration of data and responses, and prompt investigation of cases by a mobile team; this also feeds into DHIS2 system.

Evidence to date

Several pilot projects have now shown that private sector providers, including drug shops and pharmacies, can report data. Reporting is often tied to membership of a professional scheme and/or access to subsidized commodities. It is not known whether private providers would be as willing to report if these incentives were not in place.

mHealth solutions have been used in innovative ways to make reporting more user-friendly for health care workers. Mechanisms to fully integrate data from both private and public outlets can be improved.

An evaluation in Swaziland¹⁹ highlighted the need for private providers to understand the purpose of reporting and how to engage with the Ministry of Health, and to adapt the timing and structure of training to minimize impact on business. Both public and private facilities are now included in planning and programmatic decisions about malaria elimination and surveillance.

Practical considerations

HMIS recording and reporting can be viewed as an added workload burden by public health workers. This viewpoint is likely to be an even greater obstacle to reporting by private providers.

Staff at retail outlets may not be used to keeping case records. Reporting systems that are designed to capture only the minimum information required, and that are quick and easy to use, will probably be most successful.

Use of open-source technology and integrated data platforms allow the rapid analysis of data collected from private and public providers.

Financial rewards may help encourage reporting, but could motivate providers to over-report. Non-monetary benefits which link reporting to access to malaria commodities (medicines or RDTs) or insurance reimbursement could minimize this risk.

Cross-cutting strategies

In addition to the malaria-specific objectives and strategies above, the Global Fund promotes and supports a coordinated and inclusive approach to investments in health and strongly encourages countries to include resilient and sustainable systems for health (RSSH) support toward building effective public–private partnerships for scaling up health services, increasing coverage and improving quality of care. Many national programs and implementers have found that broader approaches are important for effectively engaging with the private health care sector. One key approach is **harmonization** – of case management guidelines, recommended medicines and diagnostic products, training materials, etc. – across all health care sectors as much as possible. This should aid efficient implementation and reduce potential for confusion.

Another key approach, emphasized as critical by nearly every colleague with experience in this area, is to **involve all relevant stakeholders early on** in planning processes. Bringing on board government regulatory authorities (e.g. food and drug administration, health facility inspectors, customs and manufacturing inspectors, etc.), the MOH/NMCP, and representatives of the private sector (professional associations, medicine and diagnostics importers and distributors, facility owners, etc.) from an early stage increases the sense of joint ownership and cooperation for programs and interventions, and improves the likelihood of sustained cooperation. A colleague from the Ghana Ministry of Health summarizes experience from several countries: “Stakeholder engagements to ensure ownership by major stakeholders is key. This helps to serve as checks on agreed directions and it provides support when there are challenges.”¹⁸

In addition, in various countries, other cross-cutting approaches have been tried to improve the quality and coverage of child or maternal health services, or general health services, in the private sector.^{21, 22} Examples discussed here include regulation, accreditation, and social franchising. **Regulation** refers to rules, laws, policies, and standards that are established to control the activities of the private health care sector. Examples of regulation include registration and/or licensing of providers; setting standards for provider qualifications and facilities; and registration of medicines, diagnostics and equipment. Agencies and authorities responsible for regulation should be given adequate resources to enforce existing policies, and to administer sanctions for non-compliance. An example of an integrated regulatory approach is the Kenya Patient Safety Impact Evaluation (KePSIE). Kenya is implementing a package of regulatory reforms for public and private health facilities, including the use of an electronic Joint Health Inspections Checklist that covers all regulatory agencies, increases the frequency of facility inspections, and includes a system of warnings, sanctions and time to re-inspection dependent on inspection scores, with public information on inspection outcomes. Strong regulatory capacity is a medium- and long-term priority for lower-income countries. In the near term, it may be more efficient to focus on interventions that encourage private providers to improve the quality and coverage of their care.

Accreditation is a process to formally recognize facilities or providers who adhere to established quality standards. Accreditation programs typically set standards for facility infrastructure, staff qualifications, completion of training (e.g. on health conditions, medicines, and business practices),

and record keeping and reporting. Incentives might include legal permission to offer certain diagnostic services or stock some prescription-only medicines. Accreditation is increasingly common in middle-income countries, where it is often a condition for reimbursement under national health insurance (e.g. in Kenya, Malaysia, Philippines, Thailand).¹² Accreditation is a relatively expensive approach, and the cost must be borne by participating facilities and eventually their patients/clients.

Step-by-step guidance

Social franchising aims to enhance health service delivery by linking existing private health care providers in a network to provide service with a common brand. The purpose is to meet public health goals of improving access to good-quality treatment, rather than purely financial gain. Provider incentives for joining franchises might include brand recognition and marketing, training, and preferential access to commodities. In Southeast Asia, well-known examples of social franchises are Sun Quality Health and Sun Primary Health in Southeast Asia, which are networks of private doctors and community health workers that provide malaria treatment, in addition to family planning and other health services. In Africa, examples include the Tunza Family Health Network in Kenya, the Familia social franchise in Tanzania, and the Top Réseau in Madagascar; these all provide integrated services for family planning and reproductive health, malaria care, and child health services through a network of accredited health facilities. Improvements in client satisfaction and perceptions of quality have been documented for many social franchises; but the effect on actual clinical quality of services is not consistent in those that have been studied.^{23, 24}

For each step, consider all actors and stakeholders that need to be involved, and all supporting interventions and strategies – and budget for them. An additional useful resource expected to be available in 2017 is the aforementioned WHO and UNITAID ‘Roadmap’ for introduction of RDTs in the private sector.

1) Assess the current private sector provision of malaria care in the country:

- a) To what extent does the private sector contribute to health care, and specifically to fever/malaria case management, in the country? Is there regional variation? Which providers serve poorer groups? (Sources of information may include DHIS, MIS, and/or household surveys done in recent years; and ACTwatch outlet surveys at <http://www.actwatch.info/publications>, filter “Type = survey reports”.)
- b) If the answers to item (a) are not already known, consider ways to obtain representative information in a timely way.
- c) What, if any, interventions have already been implemented / tried for engagement with the private health care sector, specifically for malaria case management, and more generally? What are the results?
- d) Identify any existing policies and regulatory frameworks that are relevant to malaria case management in the private sector (importation and registration of medicines and diagnostics, policies that affect who may provide clinical and diagnostic services within a country, prescription-only status of medicines etc.).

2) **Identify all relevant authorities and stakeholders early on**, to ensure a sense of joint ownership of the planning process, cooperation and sustainability of future interventions. Consider government agencies, non-governmental organizations, manufacturers / importers / distributors, laboratory professionals, private providers, owners and managers of private pharmacies/facilities, professional associations, etc. Note: This step can easily be overlooked, which has caused problems in some countries. In addition, some countries have more than one regulatory authority, for example, with different but overlapping objectives and mandates.

- 3) **Check existing national policies early on** to see whether they support potential interventions/programs in the private sector. If not, plan for how to align potential programs with existing policies, or how to foster policy change. Some countries have found that implementation of malaria RDTs in private outlets is blocked or delayed by existing policies that ban diagnostic testing in private outlets.
- 4) **Develop a short-list of strategies that may be most suitable to the country context/s.** Ideally, this will be done in consultation with the stakeholder group identified in step 2.
- 5) **Seek out more information on those strategy options that appear most suitable** for your country context/s. This involves fact-finding on strategies of potential interest, through review of reports and documents, and discussion with experienced implementers. What lessons have been learned elsewhere? Bring back this information for discussion by stakeholders and decision-makers, and discuss how to apply the ideas in your country's context/s.
- 6) **Consider seeking legal guidance on policy implications, regulatory issues, etc.**
- 7) **Solicit views from local stakeholders, and then make decisions: select what to do, which strategies to take on.** For example, a country could choose to begin by focusing just on horizontal regulation of commodities and some case management services.
- 8) **For each strategy to be implemented**, identify specific agencies and individuals to be responsible; agree on a timeframe, and outcomes/objectives to be monitored and reported on.
- 9) **Implement the strategies.** The responsible people for each strategy should be accountable for ensuring timely coordination of the activities that must be harmonized (e.g. procurement and distribution of commodities, training and communication campaigns, etc.).
- 10) **Monitor the outcomes for each strategy.** Arrange regular opportunities for stakeholders to discuss results and progress, and agree on any adjustments and corrections that may be needed. The Global Fund encourages countries to consider requesting funding to support private sector case management, especially if the private sector contributes significantly to service delivery. Requests should include a well-described, feasible strategy encompassing the different, applicable aspects outlined in this document.

Citations

1. World Health Organization. World malaria report 2015. In: Global Malaria Program, editor. Geneva, Switzerland; 2015.
2. Cohen JM, Woolsey AM, Sabot OJ, Gething PW, Tatem AJ, Moonen B. Public health. Optimizing investments in malaria treatment and diagnosis. *Science* 2012; **338**(6107): 612-4.
3. Team AIE. Multi-Country Independent Evaluation Report: Independent Evaluation of the Affordable Medicines Facility - malaria (AMFm) Phase 1. 2012.
4. AJTMH supplement. The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Implications. *Am J Trop Med Hyg* 2015; **2015 Jun**; **92**(6 Suppl :39-50. doi: 10.4269/ajtmh.14-0391).
5. Risha PG, Msuya Z, Clark M, Johnson K, Ndomondo-Sigonda M, Layloff T. The use of Minilabs to improve the testing capacity of regulatory authorities in resource limited settings: Tanzanian experience. *Health Policy* 2008; **87**(2): 217-22.
6. Kovacs S, Hawes SE, Maley SN, Mosites E, Wong L, Stergachis A. Technologies for detecting falsified and substandard drugs in low and middle-income countries. *PLoS One* 2014; **9**(3): e90601.
7. Newton PN, Caillet C, Guerin PJ. A link between poor quality antimalarials and malaria drug resistance? *Expert Rev Anti Infect Ther* 2016; **14**(6): 531-3.
8. UNICEF Supply Division. Malaria Rapid Diagnostic Tests Market & Supply Update. UNICEF; 2016.
9. Tougher S, Group AC, Ye Y, et al. Effect of the Affordable Medicines Facility--malaria (AMFm) on the availability, price, and market share of quality-assured artemisinin-based combination therapies in seven countries: a before-and-after analysis of outlet survey data. *Lancet* 2012; **380**(9857): 1916-26.
10. ACTwatch Group and Population Services International/Cambodia (PSI/K). ACTwatch Study Reference Document: Cambodia Outlet Survey Trends, 2009, 2011, 2013 and 2015. Washington DC: PSI.; 2016.
11. ACTwatch PSIa. ACTwatch Outlet Survey Results Cambodia, 2009-2015. Washington DC: USA; 2016.
12. Mbonye AK, Clarke SE, Lal S, et al. Introducing rapid diagnostic tests for malaria into registered drug shops in Uganda: lessons learned and policy implications. *Malar J* 2015; **14**(1): 448.
13. Mbonye AK, Magnussen P, Lal S, et al. A Cluster Randomised Trial Introducing Rapid Diagnostic Tests into Registered Drug Shops in Uganda: Impact on Appropriate Treatment of Malaria. *PLoS One* 2015; **10**(7): e0129545.
14. Awor P, Miller J, Peterson S. Systematic literature review of integrated community case management and the private sector in Africa: Relevant experiences and potential next steps. *J Glob Health* 2014; **4**(2): 020414.
15. Awor P, Wamani H, Tylleskar T, Jagoe G, Peterson S. Increased access to care and appropriateness of treatment at private sector drug shops with integrated management of malaria, pneumonia and diarrhoea: a quasi-experimental study in Uganda. *PLoS One* 2014; **9**(12): e115440.
16. Haas S. mHealth Compendium, Special Edition 2016: Reaching Scale. Arlington, VA: African Strategies for Health, Management Sciences for Health; 2016.
17. Bridges DJ, Winters AM, Hamer DH. Malaria elimination: surveillance and response. *Pathog Glob Health* 2012; **106**(4): 224-31.
18. Aubyn V, Ghana Ministry of Health. personal communication. interview ed; August 2016.

19. Bennett AA, Anton LV; Wegbreit, Jennifer; Cotter, Chris; Roberts, Kathryn; Gosling, Roly D. Background Paper: The Private Sector's Role in Malaria Surveillance. In: Global Health Group at the University of California SFU, editor.; 2014.
20. International R. Coconut Surveillance: Open-source mobile tool designed to take on malaria, other infectious diseases. 2016. <https://www.rti.org/impact/coconut-surveillance2016>).
21. Montagu D, Goodman C. Prohibit, constrain, encourage, or purchase: how should we engage with the private health-care sector? *Lancet* 2016; **388**(10044): 613-21.
22. Montagu D, Goodman C, Berman P, Penn A, Visconti A. Recent trends in working with the private sector to improve basic healthcare: a review of evidence and interventions. *Health Policy Plan* 2016; **31**(8): 1117-32.
23. Beyeler N, York De La Cruz A, Montagu D. The impact of clinical social franchising on health services in low- and middle-income countries: a systematic review. *PLoS One* 2013; **8**(4): e60669.
24. Nijmeijer KJ, Fabbriotti IN, Huijsman R. Is franchising in health care valuable? A systematic review. *Health Policy Plan* 2014; **29**(2): 164-76.