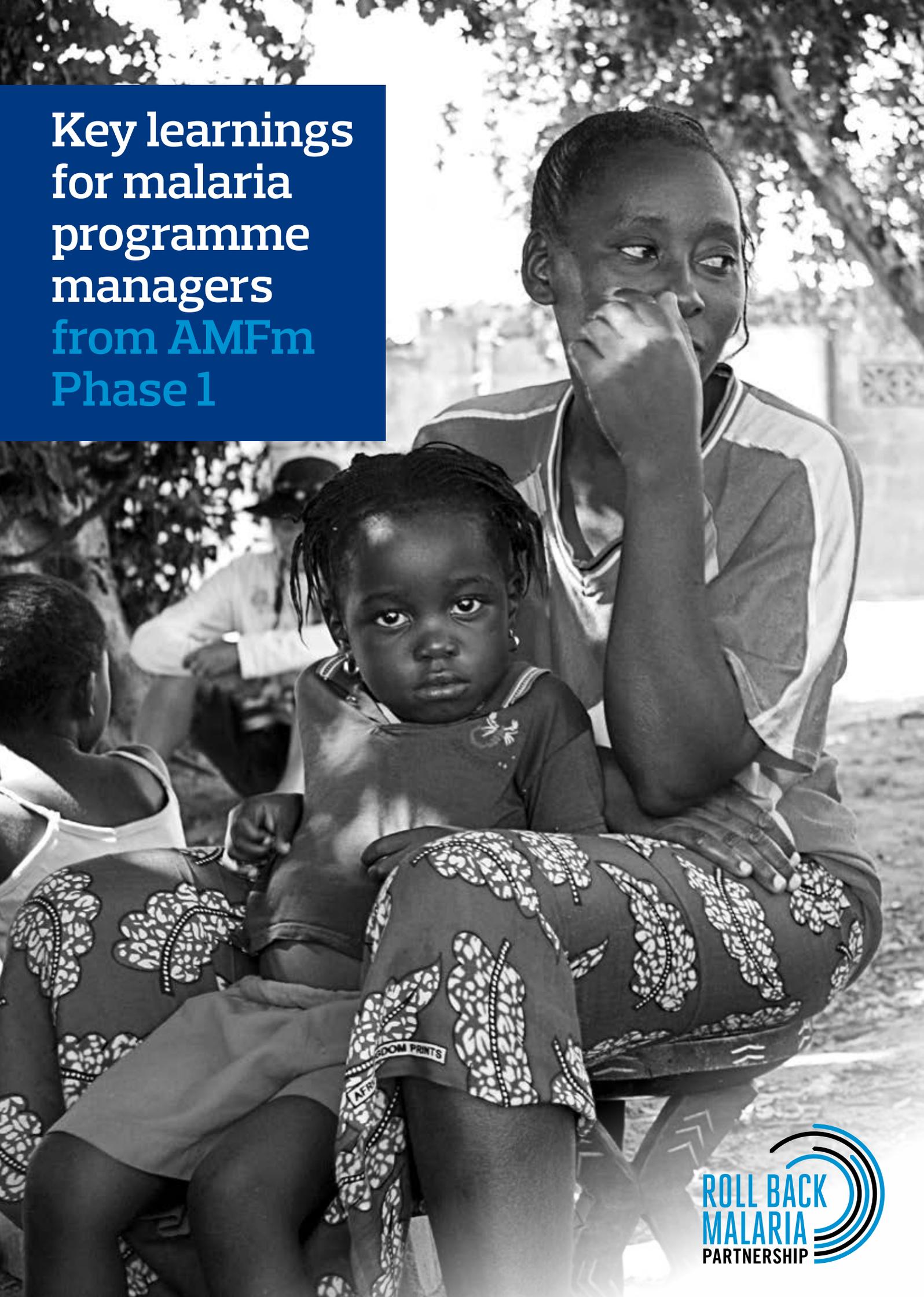


**Key learnings
for malaria
programme
managers
from AMFm
Phase 1**



Abbreviations

ACT	Artemisinin-based Combination Therapy
ADDO	Accredited Drug Distribution Outlet
AMFm	Affordable Medicines Facility – malaria
CHAI	Clinton Health Access Initiative
FLB	First Line Buyer
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
IE	Independent Evaluation
M&E	Monitoring & Evaluation
oAMT	Oral Artemisinin Monotherapy
OTC	Over-the-Counter
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RRP	Recommended Retail Price
SI	Supporting Intervention
SP	Sulphadoxine/pyrimethamine

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The Roll Back Malaria (RBM) Partnership is the global framework for coordinated action against malaria. Founded in 1998 by UNICEF, WHO, UNDP, and the World Bank, and strengthened by the expertise, resources, and commitment of more than 500 partner organizations, RBM is a public-private partnership that facilitates the incubation of new ideas, lends support to innovative approaches, promotes high-level political commitment, and keeps malaria high on the global agenda by enabling, harmonizing, and amplifying partner-driven advocacy initiatives. RBM provides policy guidance and secures financial and technical support for control efforts in countries and monitors progress towards universal goals. The RBM Secretariat is hosted by the World Health Organization in Geneva, Switzerland.

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Foreword by the Executive Director, Roll Back Malaria Partnership

This Key Learnings Summary informs malaria programme managers and decision makers of the lessons learnt since 2010 from implementing the Affordable Medicines Facility – malaria (AMFm) nationally in eight malaria programmes in seven countries: Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania mainland, Uganda and Zanzibar.

In these countries, as in many countries around the world, malaria patients or their carers seek their treatment from the closest source, most likely private retail outlets, such as pharmacies, drug shops or medicine sellers. Unfortunately, the antimalarials they were buying there were the ones they could afford: older less-effective antimalarials such as chloroquine and SP. The Artemisinin-based Combination Therapies (ACTs), recommended by WHO as first-line treatment, were too expensive and often not even available for sale in retail outlets in remote areas.

To address this situation, the Roll Back Malaria Partnership designed AMFm and invited the Global Fund to Fight AIDS, Tuberculosis and Malaria, which agreed, to host and manage it. By mid-2010 private importers of medicines in the seven countries were able to buy ACTs at a highly subsidized price, making them as cheap as chloroquine, with AMFm co-paying over 90% of the bill.

Conducted after only one year of implementation, an extensive Independent Evaluation demonstrated the performance of the private sector in distributing ACTs nationwide, increasing availability at affordable levels in only a few months, including in remote areas. The Independent Evaluation has been rigorously reviewed by many groups of experts and published in the peer-reviewed literature. Additional studies have also shown that subsidizing ACTs for the private sector seems to have a beneficial effect on access to ACTs by febrile children less than five years old, including in the lowest socio-economic groups. The Global Fund has decided to incorporate AMFm principles in its new funding model, so allowing countries, where a similar approach would be of benefit, to include in their funding requests subsidies for ACTs in the private sector (and Rapid Diagnostic Tests as appropriate).

As a community we have set ourselves demanding targets of coverage with quality diagnosis and treatment in the private healthcare systems by 2015. Therefore, the Board of the Roll Back Malaria Partnership has requested that the key learnings from implementing AMFm be shared as widely as possible. I thank the AMFm Taskforce for pulling together this excellent summary of lessons learnt. My gratitude also goes to the Global Fund for having accepted to host and manage the AMFm and to the many Partners who contributed financially, technically or otherwise to the successful deployment of the AMFm.

I invite malaria programme managers and decision makers to consider carefully whether a similar approach of subsidizing ACTs (and RDTs) for the private retail sector in their countries would be of benefit and could be included in their strategic and operational plans and proposals for financing.

Dr Fatoumata Nafo-Traoré

Executive Director
Roll Back Malaria Partnership
June 2013





**Key learnings
for malaria programme
managers
from AMFm Phase 1**



The Affordable Medicines Facility – malaria (AMFm) was an initiative hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and piloted in 2010–2012. Its objective was to look at the impact of a manufacturer-level co-payment system on the accessibility and affordability of effective antimalarials in both the public and private sectors.

This document draws together all of this available information to inform national malaria control programme managers and their colleagues on the key learnings from AMFm Phase 1 and related studies. It is not intended to be a report on the findings of the Independent Evaluation of Phase 1 of AMFm. Key findings can be found in the report of the Independent Evaluation team [1,2]. This is to help national malaria programme managers with their decision on whether a similar approach would be of benefit in their particular country setting, and to aid them in drafting their grant proposals to the Global Fund or bilateral aid donors. It does not recommend any particular approach (especially the involvement of the private retail sector) but leaves this to the national programmes to decide, based on their local circumstances.

Background

Access to quality and effective antimalarial drug treatment is a key part of the efforts to control and eliminate malaria. The introduction of Artemisinin-based Combination Therapy (ACT) in the early 2000s and their inclusion in the World Health Organization (WHO) Treatment Guidelines [3] was a major step forward in enabling effective treatments, especially where drug resistance to existing and affordable treatments (particularly chloroquine and sulphadoxine/pyrimethamine [SP]) had become a problem. However, there were several challenges to ensuring that all patients could get access to these drugs, in particular their high cost. In 2004, the Institute of Medicine recommended that a global subsidy should be introduced to enable patients and their carers to access ACTs at prices similar to chloroquine or SP [4]. This proposal was taken up by the Roll Back Malaria (RBM) Partnership who developed the concept and then by the Global Fund, who agreed to host an initial pilot. This became known as the Affordable Medicines Facility – malaria (AMFm).

The AMFm Phase 1 ran between June 2010 and December 2012 in seven Sub-Saharan African countries (eight pilot programmes). An Independent Evaluation (IE) of its success in reaching key pre-set success parameters was reported in the second half of 2012. The Global Fund reviewed the results of the AMFm Phase 1 and the findings of the IE in November 2012 and agreed to incorporate its principles into its new core financing model, with the subsidy (or co-payment model) being restricted to the private retail sector. The Global Fund Secretariat has now issued an Information Note on this [5].

In addition to the results of AMFm Phase 1 as assessed by the IE, several other groups carried out studies on the impact of AMFm on various parameters. There have also been studies reported in the literature on the impact of other related approaches to making antimalarials more accessible to patients.

Challenges to Effective Treatment

AMFm was designed to overcome the following challenges to the effective use of ACTs in malaria-endemic countries.

1. Accessibility

In many malaria-endemic countries, patients access treatment for fever (which can often be thought to be the same as malaria) not only from the formal healthcare system (hospitals, clinics, public sector channels) but also from private sector outlets. These can be formal (clinics, hospitals, pharmacies, authorised drug shops) or informal/over-the-counter (OCT; such as unauthorised drug shops, grocery shops, market stalls, and itinerant vendors).

While treatment may be accessed for free or at a highly subsidised level through public sector outlets, these may be difficult to access physically because they are some distance from the patient's home, need prolonged waiting to see a healthcare professional, or may not be open at times convenient to the patient or their carers [6]. In these situations, the private sector plays an important role in supplying treatment to patients in a timely fashion. WHO recommends parasitological confirmation by microscopy or alternatively RDTs in all patients suspected of malaria before treatment is started. Treatment solely on the basis of clinical suspicion should only be considered when a parasitological diagnosis is not accessible. In many countries the most convenient and most used source of treatment is the private sector, often the informal retail outlets. Here, ineffective drugs such as chloroquine and SP can be available, but ACTs are not. This is either due to the high price of the drugs, resulting in poor demand, or the drugs are not registered as over-the-counter and so legally cannot be sold.

2. Affordability

ACTs are expensive drugs to manufacture. This is principally due to the cost of the artemisinin component in the combination. Artemisinin is obtained by extraction from the *Artemisia annua* plant and the cost of this has been high and very volatile over the last ten years. In addition, the other component of one of the major ACTs – lumefantrine – also has a relatively high cost of manufacture. Although efforts have been made to reduce the cost of ACTs as much as possible, at present it has not been proved possible to get this below about US\$1/course of adult treatment. At this level of factory gate prices, the ultimate price to a patient has been up to US\$10/treatment. This is obviously far too expensive for most patients, especially in rural areas, whose disposable income may be in the range of US\$ 1-2/day.

3. Sub-standard drugs & monotherapies

Sub-standard drugs are a major concern in delivering high-quality treatment to patients in many countries, especially those with weak or under-resourced regulatory systems. These may include drugs that are outright counterfeits of quality-assured brands and are deliberately intended to be passed off as the original product: others may include registered products that are not being manufactured to the same standards as quality-assured products and so the guarantees that the products contain the active ingredients in the labelled quantities are not as robust as for the quality-assured products. The use of sub-standard drugs to treat any infectious disease, including malaria, runs the risk of patients taking sub-therapeutic doses of the drugs and so helps to accelerate the selection of resistant strains of the infective agent. Therefore, it is vital to efforts to preserve the utility of drugs such as ACTs to find ways of ensuring that patients only use properly quality-assured products in the correct doses for the correct period of time.

A particular concern was the availability in some countries of artemisinin monotherapies. Use of these drugs, even if manufactured to international quality standards, still carried a major risk of inducing resistance to the artemisinin derivatives. Artemisinin monotherapy requires at least seven days of treatment at adequate doses to be fully effective. Treatment for less than this duration selects out the resistant strains of *Plasmodium* parasites. The absence of another antimalarial with a different mode of action also promotes resistance development as the strains that survive exposure to artemisinin do not then have any exposure to the partner drug.

Elements of AMFm Design

AMFm has three key elements in its design.

Price Reductions

Through negotiations with the companies who can manufacture ACTs to the quality standards required by the Global Fund, the ex-manufacturer prices were reduced as far as possible. In some cases, the companies announced that these prices were on a “no profit, no loss” basis. The public and private sector prices were aligned. The AMFm Unit within the Global Fund Secretariat commissioned a negotiating agent to consult with all eligible ACT manufacturers to assess the maximum prices for co-paid ACTs, and make recommendations to the Global Fund on any applicable changes based on a comprehensive assessment of the ACT and API markets. The Global Fund Secretariat then reviewed these recommendations and set the maximum prices and co-payment amounts.

Co-payment

In order to further reduce the price at which the “first-line buyer” (FLB)¹ in a country could buy the ACTs, a co-payment to the manufacturer was introduced. This co-payment was the difference between the ex-factory price of the ACT (e.g. US\$1.00/course of treatment) and a target price of US\$0.05/course of treatment. The co-payments were standardized across all the pilot countries, and included the costs of freight and insurance.

Supporting Interventions

Simply making the ACTs available at the top of the supply chain at an affordable price does not guarantee that they will reach the patients, especially those in most need and furthest from the FLBs. The AMFm model relies on demand for the drugs “pulling” them through the supply chain in the same way that most consumer goods are pulled through by demand and the distribution system responding to that demand. Therefore, a series of “supporting interventions” (SIs) were developed to create the demand, to facilitate the availability of the ACTs, to promote their appropriate use, and to ensure that participants in the supply chain did not exploit the low prices and profit from the low price to the FLBs.

These SIs included (not necessarily in all pilot countries):

- **Regulatory Interventions:** the necessary regulatory changes needed to ensure that the ACTs could be made available in all the outlets where patients access antimalarial treatment.
- **Recommended Retail Prices:** the setting of recommended retail prices (RRPs) so that patients knew what prices they could expect to have to pay for the drugs and to minimise profiteering in the supply chain.
- **Advocacy & Behaviour Communications:** in order to inform the population about the availability of ACTs, their effectiveness compared to older drugs such as chloroquine, the RRP (where set), and other key information needed to create demand and encourage appropriate use, mass communication programmes were needed.
- **Supplier Training:** training programmes to inform people working at various levels in the distribution system about the new drugs and the workings of the system were needed to ensure proper distribution, storage, and use of the ACTs.
- **Quality Logo:** all ACTs supplied under the AMFm pilot programmes bore a “Green Leaf” logo to identify the brands that were not only ACTs, but were eligible for the co-payment – as they met the quality standard recognised by the Global Fund and their manufacturers had signed supply agreements with the Global Fund.



FIGURE 1 > AMFm “Green Leaf” logo

1. A “first-line buyer” is the company buying from the manufacturer and importing the drug into a country. The FLB then sells the drug onwards into the distribution system in the country through which the patient will ultimately access the ACT.

Key Learnings from Phase 1 and Other Related Studies

Full details of the findings of the Independent Evaluation are available from the IE Report [1] and are not repeated here. This section outlines the key learnings that may be of use to programme managers. It also includes learnings from other studies carried out alongside the AMFm pilots to test the impact of the AMFm design on other aspects of improving access to ACTs. There are also a range of studies on the impact of subsidies on the use of a variety of health-related commodities and on the use of the private sector as a vehicle to increase access to these commodities. A review for the RBM Board has summarised these [7].

Impact on the Private Sector

AMFm has had a significant impact in the private for-profit sector for all but two of the pilots (where there were special circumstances). There were dramatic impacts on the antimalarial market, through large increases in ACT availability, decreases in ACT prices, and increases in ACT market share. These changes were substantial and achieved in only a few months, demonstrating the power of tapping into the distributional capacity of the private sector. The private for-profit sector response was similar in rural and urban areas, in some cases reducing or closing a rural-urban gap in availability and market share.

Impact on the Public Sector

In the AMFm Phase 1, fewer fundamental changes to the public sector antimalarial supply were seen. This was put down to problems in ACT procurement and grant disbursements, leading to substantial delays in ordering. In most countries, ACT procurement is already donor-supported and ACTs are supplied free-of-charge in public health facilities and so the impact of the AMFm model in increasing access to ACTs is not as relevant as it is to the private sector.

Impact on Pricing

Where a co-payment system was introduced, prices to end-users fell rapidly and considerably over the time period available for the IE to measure. There was little evidence that intermediaries in the distribution system were unduly profiting from the low prices that the ACTs were being sold to the FLBs. The introduction of RRP also seems to have ensured that profiteering was kept to a minimum.

In the private retail sector, the price of co-paid ACTs varied significantly from country-to-country (range US\$0.51 to US\$1.96). Reasons for these variations may include (i) variations in RRP and their promotion, (ii) guidelines on mark-ups, (iii) differences in cost

structures including tax rates, (iv) time since co-paid ACTs first arrived in the country.

There is also evidence of some degree of price elasticity in the level of the co-payment. Work has been undertaken in rural Kenya among more than 2,700 care-seekers accessing antimalarials in four drug shops in four rural market centres. This study has shown that a subsidy of 80% rather than 90% did not have a significant impact on the purchases of ACTs by users [8,9]. So long as the final price to patients is affordable, then the level of the subsidy can be adjusted to free up resources to extend the coverage of the co-payment scheme, introduce additional elements (e.g. diagnostic testing), or improve monitoring and evaluation systems (M&E).

Impact on Availability

The impact of the introduction of the co-payment system also resulted in a rapid and significant increase in the availability of ACTs bearing the "Green Leaf" logo, especially in the private retail sector.

In the eight pilot programmes, availability of ACTs increased significantly in five countries (range between 35 to 52 percentage points), and showed small increases in two (Niger and Madagascar) where there were special circumstances.

A key concern throughout the piloting of AMFm was that the co-paid drugs would only be available in urban areas and that people living in rural or remote areas would not have access to them. However, several studies have shown that in a relatively short space of time co-paid ACTs could be found in remote areas, indicating that if demand was created, then the distribution system would respond to meet it. This emphasises the importance of the SIs, which will be referred to later.

Panel 1: ACT Availability in Remote Areas of Tanzania

A study of the trend in availability of co-paid ACTs during the AMFm pilot has been carried out in Tanzania [10]. It showed that there was a large increase in the availability of low-priced ACTs with no significant variation due to remoteness. The figure below shows the probability of co-paid ACTs (ACTm) being stocked in two regions of Tanzania (Rukwa & Mtwara), both considered remote from the main centres of population. Rukwa is 1,150 km from Dar es Salaam, and Mtwara is 556 km. In both regions, the availability of co-paid ACTs increased over the course of the study – between February 2011 and January 2012. The differences between the regions were not statistically significant. The increases in availability happened without any specific activities targeted at remote areas.

FIGURE 2 > Spatial distribution of AMFm–ACT stocking over five rounds of surveys [Source: Yadav *et al.* Ref. 10]

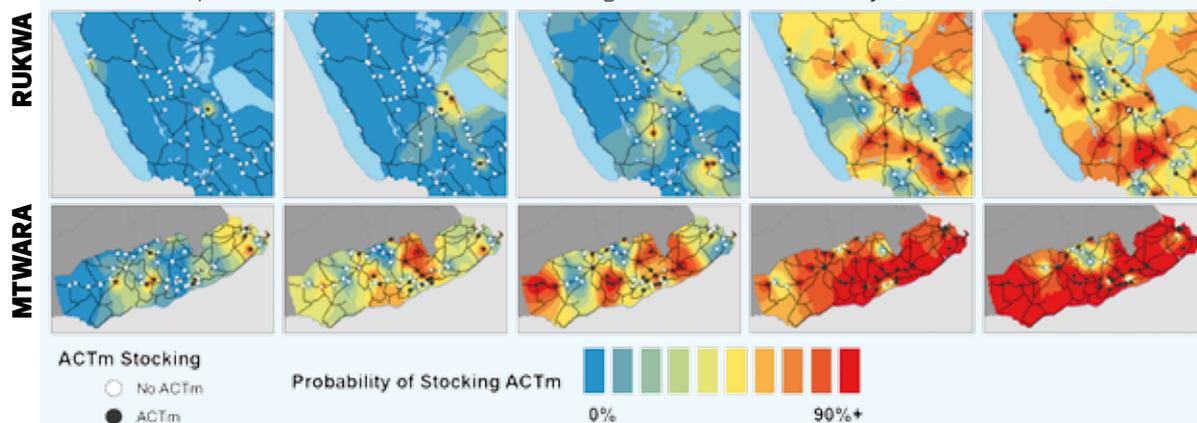


TABLE > Percentage of shops stocking AMFm–ACT by region and survey round

	Overall		Mtwara		Rukwa	
	N	%	N	%	N	%
R1: Feb 2011	255	12.55	110	24.55	145	3.45
R2: Apr 2011	253	26.09	109	50.46	144	7.64
R3: May 2011	237	37.55	102	61.76	135	19.26
R4: Aug 2011	234	66.67	97	87.63	137	51.82
R5: Jan 2012	243	73.25	102	88.24	141	62.41

Impact on Market Share

The use of the co-payment system to reduce the price of ACTs to affordable levels also resulted in a significant increase in the market share of ACTs purchased by patients and their carers. Four country programmes showed significant increases of more than 10 percentage points (range 18 to 48). Two programmes showed no effect, but again there were special circumstances that could account for this. The highest increases in market share were in those countries – Ghana, Kenya – where the AMFm pilot programme ran for the longest period.

Therefore, not only were retail outlets stocking the products, but the demand created by the SIs was also reflected in which drugs people were actually buying. There was some evidence that co-paid

drugs were beginning to crowd out sub-standard and ineffective treatments, and this effect was again most pronounced in countries where the pilot programmes had run for the longest period (Ghana, Kenya).

It was found that the availability of oral artemisinin monotherapies (oAMTs) was not a problem in most pilot countries (except Nigeria and Zanzibar). Regulatory changes that had been implemented before the advent of AMFm to ban the use of oAMTs had already been successful in reducing the availability of these drugs where this was measured. Success benchmarks for "crowding out" artemisinin monotherapies were met in all pilots where the amount of artemisinin monotherapies in the market made these benchmarks relevant, and combining enforcement of regulatory action alongside implementation of AMFm appears to have had a dramatic effect, particularly in the case of Zanzibar.

Impact on Usage

There has been concern about the ability of an AMFm-type subsidy model to increase access to ACTs among vulnerable groups. Of particular interest are children under-five with fever, people living in remote and/or rural areas, and different socio-economic groups. The availability of ACTs in remote areas has already been discussed.

Treatment of Fever in Under-Fives

The evidence for the impact of the AMFm model on ACT usage has been derived from various household surveys. It shows that usage in treating fever in children under-five has increased (see Fig. 3) [11].

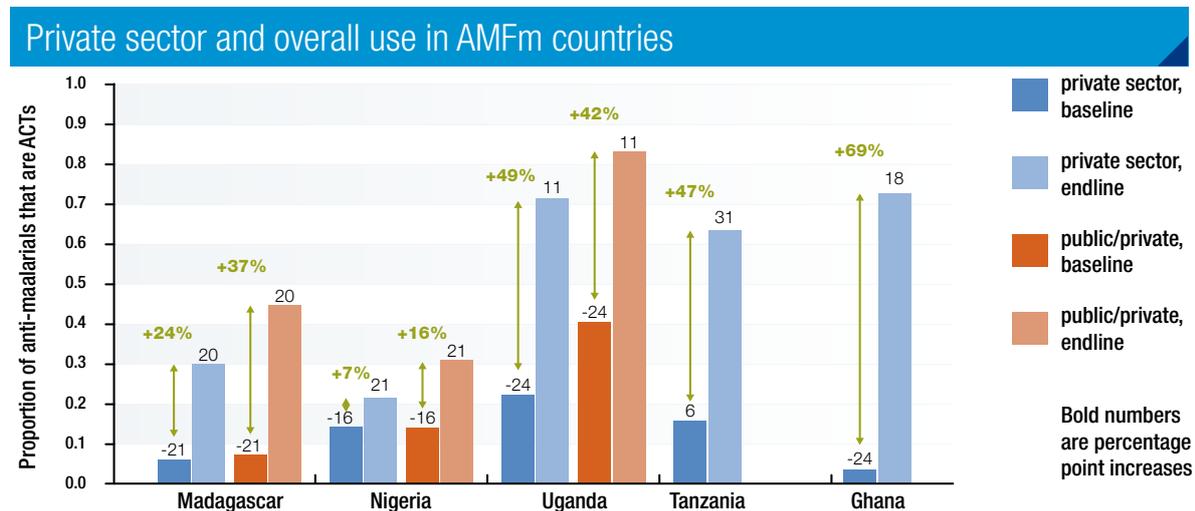


FIGURE 3 > Of those obtaining antimalarials from the private sector to treat children under-five, the proportion that obtained an ACT (by country) [Source: CHAI]

Socio-economic Groups

Analysis by the Clinton Health Access Initiative (CHAI) on changes in usage during the implementation of AMFm analysed by socio-economic status (SES) has shown that there appears to be little difference in the impact between the highest and lowest groups (see Fig. 4) [11].

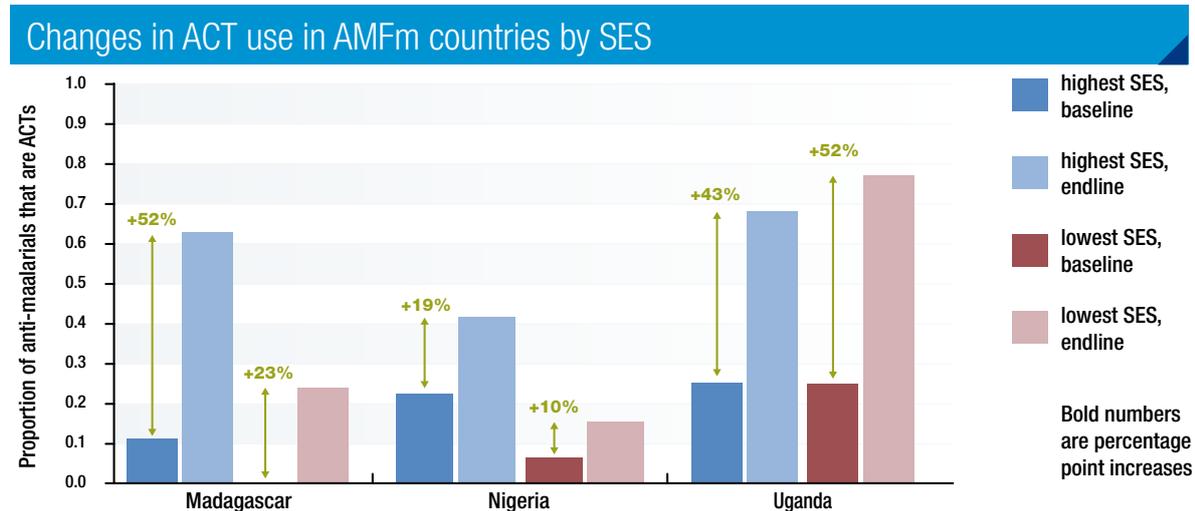


FIGURE 4 > Increases in usage of ACTs in the private sector by children under-five in the lowest and highest SES [Source: CHAI]

Treatment of Non-malarial Fevers

If antimalarial drugs are routinely bought to treat fevers in all malaria endemic areas regardless of transmission intensity, many of the fevers will be non-malarial and incorrect treatment will occur. The study in rural Kenya found that subsidised ACTs were bought for non-malarial fevers in adults in 75% of cases [9]. Reducing the level of subsidy on the ACT from 92% to 80% in this sample of patients seeking care at the four participating outlets saw the share of ACT takers testing positive for malaria increase from 56% to 75%, without compromising access.

Impact on Drug Supply

AMFm Phase 1 relied on a dedicated unit in the Global Fund Secretariat to administer the relationship with the global ACT manufacturers. This unit commissioned the negotiation of the ex-manufacturer drug prices, forecast demand to inform the manufacturers' planning, and also rationed the approval of orders and therefore of the co-payments when financial resources were constrained. This system worked well and delivered efficiencies of scale that were welcomed by both malaria control programmes and manufacturers. The private sector could buy its supplies of ACTs in the normal way from manufacturers through FLBs, was not restricted by the timing cycles inherent in public tendering procedures, and so could respond more quickly to changes in demand. Manufacturers welcomed having one group with one set of administrative processes from whom to obtain the co-payments.

In nearly all of the Phase 1 countries, fever is considered by the general public as being due to malaria. Indeed in many countries, the local language does not distinguish between fever and malaria. Therefore, the first treatment for a fever is to take an antimalarial. However, the actual incidence of malaria as a proportion of fever has been falling in many places. While ACTs should be reserved for the treatment of malaria alone, most people identify malaria purely symptomatically, by a severe fever, and seek treatment as they have for many years from a local retail outlet before seeking formal diagnosis and treatment at a health facility. It is likely that many of the ACTs ordered and passed through the distribution system were not used to treat malaria, but mistakenly for non-malarial fevers. This underlines the need for the wider availability of diagnostic testing, especially with RDTs.

Another worry was that substantial quantities of ACTs bought at the subsidised prices would be diverted into countries not participating in the pilots and where they could be sold at non-subsidised prices. Although there were some reports of this being seen [12], the quantities of drugs delivered and sold in participating countries showed that this risk was in fact quite small. It appears that the distributors of ACTs could make adequate returns from supplying large volumes at profit margins similar to those for older drugs like chloroquine, and did not need the additional profits on smaller volumes that might be obtained by diversion.

Importance of Supporting Interventions

Simply making the ACTs available at an affordable price will not be enough to ensure that they are bought and used. Demand must be created through mass communication with potential end-users. In Kenya, drug store owners "overwhelmingly" reported that customer demand was the driving factor for which drugs they stocked [6]. Similarly, to ensure the maximum availability of the drugs at affordable prices, the right enabling environment needs to be created.

1. Recommended Retail Pricing

A major initial concern about the co-payment model was that the cost-savings to the FLBs would not be passed through the distribution system to patients. In practice this did not prove to be the case, and normal mark-ups were observed. However, the setting and publicising of RRPp ensured that people knew what prices to expect to have to pay and minimised the risk of profiteering.

2. Public awareness communications

Public awareness of how to treat malarial fever is often poor and public education is essential, as shown in a study in six African countries [13]. Large-scale public communications programmes are essential to ensure that the population know that there are new and effective drugs (ACTs) now available, how they should be used, where they can be bought, and that they should be affordable. Where RRPp can be put in place, then these also need to be communicated so that the end-users can ensure that the retail outlets do not over-charge and profiteer from the subsidy scheme. The communication of the Green Leaf logo to indicate quality and effective products is also a key part of the communication messages. These communications programmes need to be coordinated with the availability of ACTs in the market, both to ensure that drugs do not accumulate on the shelves of the outlets, or that there is no stock to meet demand.

Allied to mass communications programmes, the countries where the AMFm model was successful also had good training programmes for the retail sector staff. These programmes covered the need for ACTs, the ineffectiveness of older antimalarials, the meaning of the Green Leaf logo as a mark of quality and effectiveness, and how to advise patients on the correct way the drugs should be administered. A study in Kenya has also shown that retailer training and education were found to be correlated with anti-malarial drug knowledge, which in turn was correlated with dispensing practices [14].

3. Regulatory environment

In many countries, ACTs are registered as prescription-only products and so can only be legally sold through registered medical facilities (pharmacies, clinics, hospitals, etc.). This is in contrast to older and now ineffective drugs (e.g. chloroquine) which are still widely available (legally or not) through the informal retail sector (groceries, market stalls, itinerant vendors, etc.). To maximise distribution, countries need to look at how to maximise the availability of the drugs. In some countries, ACTs have been moved to OTC status in order to maximise availability.

It is also important to ensure that people know about the availability of more effective drugs and that they are affordable. To this end it is therefore important that it is legal to communicate about ACTs to the general public. This may mean that the rules and regulations on promotion of prescription-only or OTC drugs must be modified to ensure that the general public can hear messages about ACTs.

Panel 2: Challenges of Regulatory Environment – Madagascar

In Madagascar, a radio and TV campaign was launched in April 2011 to communicate the availability of co-paid ACTs and their benefits. Unfortunately, this had to be terminated in May 2011 as it was deemed to contravene the law prohibiting advertising prescription drugs to the general public.

As mentioned earlier, the enforcement of strict regulations against the availability of oAMTs has been very successful in removing them from the market in many countries, and this will need to be maintained.

4. Alignment of drug supply & communications

At the outset of the AMFm pilots, it was common for private sector drug distributors to respond to the availability of co-paid drugs quickly and so for the supply of drugs to reach through the entire supply chain shortly after the pilot programme was launched. However, for a variety of reasons, in some countries the mass communication programmes and other elements of the SIs did not keep pace with the availability of ACTs. It was apparent from the findings of the IE that countries where mass communications followed soon after the availability of drugs and the two ran alongside one another throughout the pilot programmes were the countries where the AMFm model had the most impact.

5. Training programmes

It has been shown that adequate training of staff selling drugs to customers in countries is necessary to ensure that patients responding to the mass communications programmes meet with a knowledgeable and sympathetic response in the retail outlets. The importance of this has been seen in several studies, but one conducted by CHAI during the implementation of AMFm is a good illustration of this [15]. This study is outlined in Panel 3. Training programmes need to be aligned both with the availability of subsidised drugs in outlets as well as the mass communications programmes.

Panel 3: Subsidies plus Education increase Access in Madagascar

Between July 2011 and April 2012, a study was made of the impact of AMFm in retail drug outlets in Madagascar and of the additional impact of retailer and provider education on the appropriate use of ACTs. It included 234 retail drug shops and 163 medical providers across five regions. After baseline surveys, "academic detailers" visited a random selection of the outlets, with those outlets not receiving a visit acting as a control. "Academic detailers" educate prescribers and other healthcare providers about new drugs or protocols for treating illnesses along the lines of pharmaceutical company representatives, but with no particular interest in any one form of treatment. On average, detailers visited the selected outlets once a month between October 2011 and March 2012. Endline data was collected in April 2012.

In districts that did not receive visits from detailers, ACT stocking increased from 54% to 69% and the proportion of customers buying ACTs instead of other antimalarials doubled to 60%. However, this effect was amplified by visits from detailers. By the end of the study, 86% of shops that had not previously stocked ACTs but had received visits from detailers were stocking them, whereas only 42% of shops that did not have visits were stocking ACTs.

Shops stocking ACTs

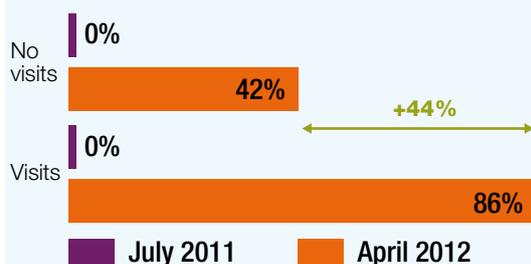


FIGURE 5 > Educational visits to shops that had never stocked ACTs doubled the effect of AMFm [Source: CHAI]

Duration of Pilot & Impact on Achievement of Objectives

AMFm was initiated in June 2010 and the IE carried out its endline measurements in the last quarter of 2011. However, the timing of the individual projects varied between 6.5 months and 16.5 months (based upon co-paid drugs being available in the country). Implementation of the SIs often trailed the availability of co-paid ACTs, in some cases by as much as 6 months. In three pilots no large-scale sustained communications programme was possible. These were arguably the three pilot programmes where AMFm had least effect on access to ACTs. Overall the duration of all the pilots in which to assess the true impact was relatively short in comparison with other similar large-scale interventions.

Longer duration of implementation appears to be positively correlated with performance, if the combined presence of co-paid ACTs and the operation of a large-scale sustained mass communication campaign are considered a proxy for full AMFm implementation. With the exception of Zanzibar, pilots with earlier start dates achieved more success benchmarks.

One key success parameter of AMFm Phase 1 was change in drug usage towards ACTs, especially in children under-five with fever. This was not measured in all of the pilot projects. The results from the IE were unclear, although the trend was in the right direction, but complicated by the small scale of some of the studies and other confounding factors. Also the duration of the pilots was relatively short to measure a significant behavioural change in the target population.

Panel 4: Summary of IE Findings in Pilot Programmes

The summary findings of the IE for each country are summarised here:

Ghana: The evidence showing impressive changes in the availability and price of co-paid ACTs, together with strong evidence of increased knowledge and awareness, the flow of co-paid drug orders and the evidence on SI implementation, provide plausible evidence that AMFm is responsible for the substantial increase observed in ACT market share. These changes are unlikely to be due to other contextual factors. The high levels of availability and market share in remote areas underline the success of AMFm in reaching more vulnerable populations.

Kenya: There were significant improvements in ACT availability, price reductions to affordable levels, and increases in ACT market share. Substantial levels of ACT availability and market share were also observed in remote areas. ACT prices in private for-profit outlets were slightly higher in remote areas, although rationing of supply may have placed upward pressure on prices by the time the remote areas survey was undertaken. The evidence about changes in the availability and price of ACTs, together with strong evidence of increased knowledge and awareness, the flow of co-paid drug orders and evidence on implementation of the communications campaign provide plausible evidence that AMFm is responsible for the substantial increase in ACT market share observed. The private for-profit and private not-for-profit sectors saw substantial and significant increases in availability.

Madagascar: Availability of ACTs and market share did not increase to a satisfactory degree, although prices did fall in comparison to the most popular antimalarial even without an RRP. There was a significant increase in ACT market share in the private for-profit sector. This limited improvement in market share was associated with the low level of co-paid drugs delivered to Madagascar, which partly reflects long delivery times, but more importantly low co-paid drug orders. Reasons for these low orders are likely to reflect low confidence by FLBs in ordering due to a lack of data on the unmet need for ACTs within the private sector and a fear of overstocking. The low level of provider and exit survey respondent awareness and understanding of the logo are no doubt due to the curtailment of the mass media campaign, which is likely to have had a substantial impact on consumer demand for ACTs. However, the Madagascar experience should be seen in the light of the recent political instability and economic challenges, which provided a highly problematic context for both the public and private sectors during the period of AMFm Phase 1.

Niger: The price of co-paid ACTs fell significantly compared to the commonly used non-ACT antimalarial. However, availability and market share did not increase to the levels desired. The amount of time elapsed between the arrival of co-paid drugs and the endline outlet survey was only around 9.5 months, so the short time for implementation could be responsible for the slow progress of the programme. However, it also seems that the quantity of co-paid ACTs ordered, particularly by private for-profit FLBs, was too low to have made much of an impact on availability and market share. The implementation of supporting interventions, which might have helped to increase demand for co-paid ACTs, and thereby might have stimulated private for-profit orders, was also derailed by delays and the suspension of disbursement of the Global Fund SI grant. Finally, the implementation context in Niger is challenging, with problems of adverse weather interrupting supply chains, difficult transport outside the main cities, and insecurity.



Nigeria: ACT market share improved during the pilot programme. There is some evidence that Nigeria also met the success benchmark for availability. Nigeria just missed the threshold for prices relative to the most popular antimalarial. The price of SP tablets was quite low, making this target difficult to meet, but there was also poor adherence to the RRP. This could reflect the relatively low awareness of the RRP. These results were achieved despite the context of instability caused by the post-election crisis and terrorist attacks, which may have affected supply in some areas. There have been impressive increases in knowledge of the first-line drug, particularly in public health facilities, but achievements in recognition of the Green Leaf logo and knowledge of the AMFm Programme were more modest, consistent with the relatively short period of implementation of SIs before the endline outlet survey was conducted (3 months).

Tanzania – mainland: There is strong evidence that in Tanzania, AMFm led to a significant increase in ACT availability and affordable prices. It is also possible that market share increased as hoped for, but the evidence is weak. However, a 10 percentage point increase in market share was easily achieved in the private for-profit sector. Data was not available on use of ACTs. The evidence about impressive changes in the availability and price of ACTs, together with strong evidence of awareness of AMFm, the flow of co-paid drug orders and SI implementation, provide plausible evidence that AMFm is responsible for the increases observed in ACT market share. These changes may also have been supported by the complementary malaria communications campaign funded by other sources.

Uganda: there is strong evidence that availability and some evidence that market share were positively affected by the introduction of AMFm. The improvements in ACT availability and market share were achieved despite the relatively short time between first arrival of co-paid drugs and the endline outlet survey (7 months) and the lack of AMFm supporting interventions.

Zanzibar: There were very substantial improvements in ACT availability and market share; reductions in ACT prices despite less than 7 months of effective implementation of AMFm, and with a relatively limited flow of co-paid antimalarials into the country. It seems appropriate to conclude, therefore, that in Zanzibar AMFm has met with a highly supportive and conducive environment. Key regulatory steps to support OTC sales of ACTs are likely to have played an important role in the achievement of the benchmarks, in addition to core AMFm interventions of the supply of co-paid ACTs and the strong communication campaign.



Incorporating the Key Learnings into a National Programme

Role of the Private Retail Sector

In many (but not all) malaria-endemic countries, the private retail sector that sells antimalarials (such as chloroquine, amodiaquine, and SP) but perhaps not legally approved to sell prescription-only products is still a key channel for patients to obtain treatment. In the AMFm IE, the private sector was a major player in the antimalarial market in all pilots, accounting for between 40% and 97% of antimalarial sales volumes at baseline, and between 49% and 92% at endline. This repeats the experience of other studies, which have been reviewed for the RBM Board [7].

Countries need to weigh up carefully the advantages of allowing these outlets to sell ACTs and so increase their availability, with the disadvantages of allowing ACTs to be widely available through informal medical channels. The response to this challenge may be to not allow widespread sale of ACTs outside of the regulated outlets (including pharmacies), to modify the classification of ACTs to permit OTC sales, introduce new classifications for outlets that can be allowed to sell the drugs (e.g. Accredited Drug Distribution Outlets [ADDOs] in Tanzania), or other approaches appropriate to each individual country.

Role of Co-payments

In many malaria-endemic countries, most treatment is delivered through formal public health facilities and the private sector has a small, if any role, in getting effective treatment to patients. In these countries, a co-payment system targeted at the private sector is unnecessary. National control programmes will be sourcing their drugs through the normal tender and centralised ordering processes, funded through government budgets, aid programmes, or other sources.

However, if patients use the private retail sector as their source of first-line treatment to any noticeable degree, then national programmes can consider the use of a co-payment system similar to the AMFm model to increase the availability of effective ACTs at affordable prices.

Managing the Supply Chain

It would be possible for a country to manage the implementation of a co-payment system to supply the private retail sector on its own. However, this would mean significant duplication of effort between countries and would also introduce inefficiencies for the manufacturers who then have to deal with multiple

organisations each with their own systems. That is a strong case for national control programmes which decide to implement a co-payment system, to retain the services of a central procurement agency acting on behalf of many countries. The staff in the Secretariat managing the private sector co-payment mechanisms hosted by the Global Fund would be the obvious group to undertake this role. Price negotiations and handling of co-payment requests from the manufacturers could remain with one body and so the handling of these transactions would be carried out in the most efficient way. Similarly, the central unit would be able to collect and consolidate forecasts of demand from countries for transmission to the manufacturers.

Country-level Customisation

Countries do not need to use exactly the same design of co-payment system and level of subsidy as was used in the AMFm Phase 1. Each country will need to consider what their priorities for access to treatment are and what resources they can make available to a subsidy scheme. As indicated in the CHAI study mentioned earlier [8,9], a subsidy or co-payment of 80% may be just as effective as one of 95%, and this will enable a larger quantity of drugs to be made available at the subsidised prices. Similarly it may be that a national programme considers that the subsidy is best applied only to certain formulations or dosage forms (e.g. paediatric) so that the most vulnerable or at-risk patient groups can easily access treatment.

Recommended Retail Pricing

Not all countries may have the necessary legal or regulatory framework to allow for the setting of RRP. In such cases it may still be possible to communicate the sort of price level that co-paid ACTs should be available at, but countries need to investigate the options.

It is important to remember when establishing RRP, that they will tend to act as much as floor prices as a ceiling on prices in the retail outlets. There may be limited incentives for retailers to sell at prices below the RRP. Therefore the RRP needs to be set in consultation with a wide range of stakeholders (not just the manufacturers or FLBs) to ensure that the RRP is set at an appropriate level for the local circumstances.

Collaboration between the Public and Private Sectors

In countries where the AMFm pilots were most

successful, there was a high level of collaboration and coordination between the public and private sectors, especially between the national control programme and the private sector. The private retail sector will need to understand the timing and content of the mass communications programmes, any changes to the regulatory environment that will be introduced to support the subsidy programme, and also be involved in the training programmes for staff to ensure that the ACTs are properly used. A coordinating committee or liaison group may be the best vehicle for this, either at national, regional, or even district level (e.g. Private Sector ACT Subsidy Task Force or Coordinating Body). It will be important for the private sector to understand how the planned programme is being rolled out so that it can plan to have the drugs in the right place at the right time.

Incorporating Diagnosis

A major concern about increasing the availability of ACTs when malaria is being treated based on a symptomatic diagnosis of fever, is the amount of drug being used by those without malaria. This is increasingly a problem as the risk of fever due to malaria falls, thanks to increased use of insecticide-treated nets and other control methods. Therefore, it is becoming more and more important for treatment with ACTs not to be initiated until a positive diagnosis of malaria is made [16]. The WHO's campaign "Test: Treat: Track" emphasises the need for prior diagnosis before initiating treatment [17].

Work in Kenya indicated that introducing a subsidy on diagnostic testing in the retail sector nearly doubled the share of illness episodes tested for malaria. Over 50% of patients who were planning to buy an ACT then chose not to do so after receiving a negative test result [9]. Another study in Uganda concluded that subsidised

RDTs can reach patients in remote areas through the private retail sector, and that this can be effective in reducing unnecessary purchases of antimalarials (see Fig. 6) [18,19].

The ACT Consortium is undertaking a series of studies looking at (1) the need for improved diagnoses and recognition of non-malarial febrile illness in retail outlets, and (2) the ways that RDTs can be introduced to retail outlets and with what level of success. These studies were not complete at the time of writing but details can be found on the ACT Consortium website (<http://www.actconsortium.org/>).

However, there are many practical challenges in extending the use of diagnostic testing (including the use of RDTs), especially into the private retail sector.

How to make the tests affordable, what to do about a negative test result, the expertise of retail staff in administering the test properly, which type of outlets should be allowed to undertake testing, and other challenges exist. The RBM Case Management Working Group is developing a best practice summary and an operational research agenda to answer questions on what needs to be understood before countries can really expand the use of RDTs in the private retail sector.

In addition, as described in a recent CHAI analysis [19], countries will need to look at the available resources to support prior diagnosis and weigh this against the risk of inappropriate treatment. This is especially true in a period of constrained resources. Countries will need to develop a robust strategy on the role of diagnostic testing and how to implement this, especially when applying to funding agencies such as the Global Fund.

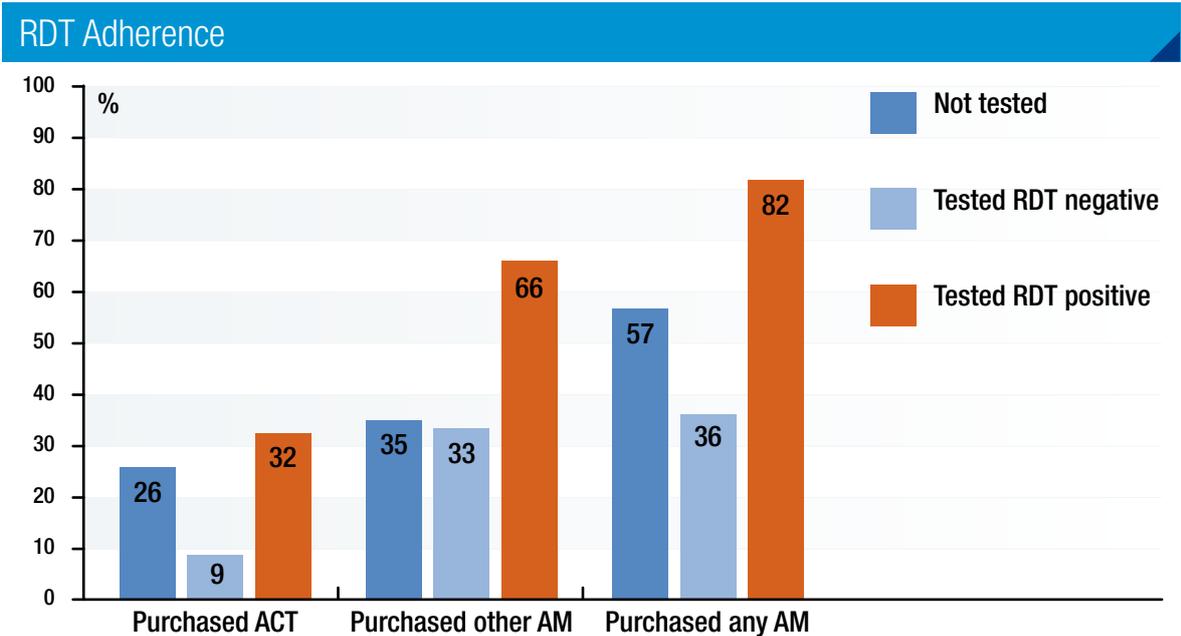


FIGURE 6 > Patients that tested positive for malaria were more likely to take antimalarial medications [Source: CHAI] [19]

Panel 5: Use of Subsidies to Promote Use of Diagnosis – Cambodia

The only documented large-scale study of the use of subsidies to promote the use of diagnosis in the private sector has been in Cambodia [20]. In this 10-year programme, diagnosis was promoted through the availability of RDTs in a social marketing programme alongside the availability of subsidised ACTs. For diagnosis, an RDT was branded to relate it to the programme. A comprehensive health education and mass communication programme was implemented, including a nationwide advertising campaign, and training of private providers. The communication programme has been undertaken over a 10-year period. The emphasis on appropriate diagnosis has increased over the years. A RRP has been established but, unlike for the ACT in the programme, this is not printed on the packaging of the test. The price has been reduced over the course of the campaign in response to the findings of a willingness-to-purchase study.

Key lessons identified were:

- despite a high degree of brand awareness being achieved through an effective communications programme for ACTs, this was much lower for the RDT.

- availability of RDTs took years to pick up and was particularly low in rural areas. This may be due in part to supply bottlenecks.

- uptake of RDTs was also much lower than for ACTs.

A key challenge for increasing the usage of RDTs, especially in the private sector, was identified as being the complexity of the message. Usually in social marketing campaigns, the message is simple, "buy this product" or "behave this way", so that the target audience can easily understand and relate. While this is also true for purchasing an antimalarial to treat visible symptoms, it is much more complex get the message across about the need to also include diagnosis. There are effectively three messages to communicate:

1. "if you are going to buy an antimalarial, only buy the recommended ACT";
2. "before you buy an antimalarial, get tested first";
3. "if you test negative, don't take an antimalarial".

In addition, there were a number of other important messages, including, for example, the importance of adherence to the recommended course and appropriate referral to the public health facilities. Where non-*falciparum* malaria is common, as in Cambodia, the message become even more complicated. The lack of clarity about what to do if the RDT is negative is a major barrier to the effective use of diagnosis in the private retail sector. For a successful adoption of RDTs and their proper use in the private retail sector, a clear and simple diagnosis and treatment algorithm needs to be developed and communicated. The strongest determinant of a patient with fever using a diagnostic test for malaria was being offered a test by the provider [21].

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