Local shop selling basic malaria medicines, Kilifi, Kenya. © Caroline Penn / Panos

SALT, SUGAR, AND MALARIA PILLS

How the Affordable Medicine Facility–malaria endangers public health

The Affordable Medicine Facility–malaria has shown no evidence that it has saved the lives of the most vulnerable or delayed drug resistance. Rather, this global subsidy has incentivised medicine sales without diagnosis and shown no evidence that it has served poor people. It poses a risk to public health and could skew investment away from effective solutions. Evidence shows that a public-public partnership between community health workers and primary health care facilities can fight malaria and deliver on other public health outcomes. But will donors listen to the evidence?

OXFAM

SUMMARY

Recent progress in controlling malaria is a major development success. Thanks to external aid and domestic financing the proportion of children in sub-Saharan Africa sleeping under a bed net has increased from 2 per cent to 39 per cent in the last 10 years.[1] This has brought down the number of malaria deaths dramatically in many countries, such as Namibia, Swaziland, Ethiopia, Senegal and Zambia, where deaths have been cut by between 25 and 50 per cent.[2]

Yet just 40 months away from the MDGs deadline, this progress is being threatened by the support of some donors for the Affordable Medicines Facility–malaria (AMFm). This facility, hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria since 2008, heavily subsidises the most effective malaria drug, artemisinin combination therapy (ACT), and promotes the sale of these medicines through informal private providers – including shopkeepers and vendors. But, as the pilot phase of the AMFm draws to a close, donors now have hard evidence of the subsidy's limitations and the risks of scaling-up, as well as better options to deliver results for poor people.

This paper reviews the limitations and failures of the AMFm, and the changes in the malaria landscape that render the AMFm obsolete. The paper also offers evidence of alternative approaches that can deliver better health outcomes for poor people. **At the Global Fund and UNITAID board meetings taking place at the end of 2012, it is essential that all donors act on the evidence, and don't continue to pursue unworkable solutions like the AMFm.**

THE UNCOMFORTABLE BIRTH OF AMFm

The AMFm was based on a 2004 study by the US Institute of Medicine, 'Saving Lives, Buying Time: Economics of malaria drugs in an age of resistance'.[3] The study concluded that the solution to malaria treatment was a global subsidy to cut the price of ACT in order to achieve two goals: a) to save lives by enhancing the availability and affordability of ACT, especially in the private sector; and b) to delay the development of drug resistance by replacing artemisinin monotherapy (AMT) with ACT thereby – 'buying time'. The use of AMT is leading to resistance to artemisinin, which, if this spreads, could render all currently available antimalarial treatments useless.

The Global Fund board decided to pilot the AMFm in a number of countries despite the various concerns raised by some board members, including the United States and the Developed Countries NGOs.

The main problems with the concept of the AMFm were, and remain, as follows:

- **Selling malaria medicines, even at a small cost, excludes poor people who cannot afford to pay for a full course of treatment.**

Evidence shows that paying for health care leads to delays in seeking treatment, or even going without it. Women are the most likely to be excluded.

- **The informal private sector does not have the ability or incentive to provide correct diagnosis and treatment.** The concept of the private sector as applied to the sale of medicines in developing countries may be misleading. It includes not only pharmacies, but also unregulated informal private sellers, such as street vendors, market stall-holders and grocers – people without medical qualifications who are motivated by commercial interest, not public health outcomes. They lack the incentive and ability to deliver correct diagnosis and treatment for malaria.
- **Many fevers are not malaria, so an informal private sector provider is the wrong place for sick people to go.** Studies in the 1990s showed that malaria was responsible of 40 per cent of fever cases in children in sub-Saharan Africa, meaning that the majority of fevers – 60 per cent – were not due to malaria.[4] Moreover, malaria cases have been decreasing in recent years. This makes it even more critical that children with a fever are diagnosed and treated appropriately – for malaria or non-malarial fevers. The informal private sector is not qualified to do so. The fact that many people currently get their malaria medicines from informal private providers is not a sound public health approach to be built on, but a dangerous outcome of a lack of investment in public provision. Not only is it dangerous for people to be given the wrong medicines, this may also contribute to worsening drug resistance.
- **The AMFm has the potential to increase resistance to malaria drugs.** The history of malaria treatment shows that chloroquine, once a cheap and effective medicine, was rendered useless against *Falciparum* malaria (the main strain in sub-Saharan Africa), partly because people could not pay for a full course of treatment. Far from delaying the development of resistance, the uncontrolled sale of subsidised ACT could lead to a similar outcome.
- **Moreover, it is unclear why AMFm is necessary**. Governments are able to use donor funding, for instance from the Global Fund and the US President's Malaria Initiative (PMI), to purchase ACT for both the public and private sectors, leaving no need for a new subsidy.

NO EVIDENCE TO CONTINUE WITH AMFm

The Global Fund Board decided at the outset that there should be an evaluation of the AMFm pilot. This was commissioned in 2010, to provide evidence for a decision at the November 2012 board meeting whether to continue, scale-up or stop the AMFm. The evaluation was intended to measure whether ACT became cheaper, was more available, displaced ineffective drugs, and was used more, especially by vulnerable populations.

Firstly, there are two considerable omissions from the evaluation:

1. The critical measure of the success or failure of the AMFm is the level of utilisation of ACT by those who actually need the medicines: confirmed malaria cases, especially children living in poor and remote areas where the public sector may not reach them. **Despite this, the use of the drugs by vulnerable populations was not systematically measured by the evaluation.**
2. The Global Fund board requested the evaluation to measure how cost effective AMFm was compared to other financing models, such as expanded public provision,[5] but the AMFm secretariat claimed this was unfeasible. This means that **evidence from countries such as Ethiopia[6] and Zambia,[7] showing decreased malaria mortality and morbidity when treatment is delivered via the public sector and community health workers (CHWs),[8] was omitted from the evaluation.** The deployment of over 30,000 health extension workers in Ethiopia (in addition to treatment and bed nets) has slashed the number of deaths caused by malaria by half in just three years.[9]

The evidence that is presented in the evaluation revealed serious problems that demonstrate the inappropriateness of AMFm to deliver malaria treatment:

- **Mixed results**: The evaluation showed different results across countries and thus cast doubt about a one-global-subsidy-fits-all model. While sales in Ghana increased dramatically, this was not the case in Niger.
- **Increased sales do not mean increased malaria treatment:** The evaluation claimed that the AMFm was a 'game changer' with 'dramatic impact on the antimalarial market through increased availability and decreased prices of ACT in the private sector'.[10] But the increased sales do not give any evidence of how many confirmed malaria cases were treated. A large proportion of the sales were for adult treatment, though morbidity and mortality rates for malaria are highest among children, and no concrete data was presented on use by poor people.[11] As a result, it is not possible to say with any certainty how many lives the AMFm pilots 'saved', or that it reached the most vulnerable.
- **The AMFm caused excessive orders of ACT, which were not based on clinical needs and led to a crisis in the global market.** For example, in 2010 there were 2,338 cases in Zanzibar, yet the private sector ordered 240,000 treatments, mostly for adults.[12] There were also excessive orders in other countries, such as Nigeria and Ghana. The total number of ACT treatments purchased by AMFm for the eight pilots was 155,812,358, nearly five times the estimated number of malaria cases in 2010 in those countries.[13] The global ACT crisis forced the AMFm secretariat to enforce rationing mechanisms, including basing orders on clinical need – a criterion that arguably should have been in place from the beginning.
- **The AMFm had hardly any impact in terms of crowding out AMT**, the use of which causes resistance. This was because the availability of AMT was already low due to governments' banning its importation and sale, and World Health Organization (WHO) efforts to restrict sales of AMT by drug companies.

THE CHANGING MALARIA LANDSCAPE IS CRUCIAL

The dramatic changes to the malaria landscape, even since the 2004 study that gave rise to the AMFm, are equally important to consider when judging the way forward. Malaria incidence has decreased from an estimated 350–500 million in 2005[14] to 216 million in 2010.[15] The price of ACT has fallen, partly due to availability of an additional producer of fixed-dose combinations and three generic alternatives. And, thanks to grants from the Global Fund and the PMI, ACT is more widely available in the public sector and through CHWs, meaning people have better options that going to informal private sector providers. Thanks to banning by the WHO and many governments AMT is now increasingly unavailable.

The WHO now recommends rapid diagnostic tests (RDTs), which are increasingly available and used by public sector and community health workers to accurately diagnose malaria. For example, in rural Cambodia, patients served by 'Village Malaria Workers' were 11 times more likely to receive a confirmed diagnosis than in areas where people used services from the private sector.[16] There is also strong evidence of the effectiveness and outreach of CHWs in diagnosing and treating malaria and non-malarial fevers in a way that informal providers cannot.[17]

THE WAY FORWARD

Policy makers must weigh the evidence and choose where the best investment is to be made to combat malaria and achieve other public health outcomes.

There is no cheap option or shortcut: whoever provides treatment must be adequately trained and supervised, meaning that any investment should be based on a thorough analysis of which model would be:

1. Most cost-effective in terms of public health outcomes (correct diagnosis and treatment of malaria and non-malarial fever), with the right training and supervision;
2. Based in the community, thus saving patients the time and expense of travel, and with sufficient knowledge of the community to provide a user-friendly service at flexible times;
3. Inclusive of children and pregnant women, and especially of poor people and those in rural and remote areas, providing them with free diagnosis and treatment;
4. Responsive to women's needs, given that the majority of carers are mothers and that malaria disproportionately affects pregnant women and children.

RECOMMENDATIONS

For the AMFm:

- The Global Fund should take a decision at their November board meeting to cease hosting the AMFm;
- UNITAID and the UK Department for International Development (the AMFm's main funders) should discontinue funding beyond current commitments (the end of 2012);
- If pilot countries wish to continue providing ACT via the private sector, they should do so through normal Global Fund or other donor grants.

For scaling-up malaria treatment:

- **Donors should invest in a public–public partnership between community health workers and primary health care facilities**, with an enhanced emphasis on training and supervision. This approach combines the benefits of public sector and community approaches, while avoiding the risk to public health entailed by the involvement of the informal private sector. It also enables a public health approach to dealing with the majority of non-malarial fevers. Professional, regulated private sector outlets, such as pharmacies, can plug gaps where they exist – normally in cities and towns. This approach is based on what works. It has already happened in countries including Ethiopia, Zambia, Rwanda, and others.

Malaria continues to be a major killer in many developing countries, with 86 per cent of malaria deaths in 2010 occurring in children under five years old.[18] With so many children's lives on the line, it is imperative that donors and governments base their decisions at the November board meeting of the Global Fund and at the December board meeting of UNITAID on evidence of what works for malaria and other pressing public health needs in developing countries.

1 INTRODUCTION

The global fight against malaria has achieved important successes. Countries such as Namibia, Swaziland, Ethiopia, Senegal and Zambia have cut deaths by between 25 and 50 per cent.[19] Thanks to external aid and domestic financing the proportion of children in sub-Saharan Africa sleeping under a bed net increased 20-fold in the last 10 years, from two per cent to 39 per cent,[20] and new, effective treatment has replaced old medicines in the public sector and in the hands of community health workers (CHWs).

Yet malaria remains a public health challenge and a major killer of children in many developing countries. In 2010, 86 per cent of malaria deaths occurred in children under five years old.[21] Repeated malaria infections also drain household resources, especially those of poor people, who pay for treatment. The goal of controlling and eventually eliminating malaria requires:

1. Scaling-up prevention through the provision of free bed nets and indoor sprays;
2. Scaling-up diagnosis and treatment using artemisinin combination therapy (ACT), especially for poor people in rural and remote areas;
3. Assurance that only confirmed cases of malaria are treated with ACT, and that non-malarial fevers are correctly identified and treated;
4. Strategies to halt the spread of drug resistance.

Achieving the above actions requires a global investment of $5.9bn annually between 2011 and 2020,[22] after which the cost would come down. Despite the increase in funding over the past few years, a gap of about $9.7 billion for the period of 2012–15 remains.[23]

The recent global focus on malaria control – and eventual elimination – has concentrated primarily on delivering subsidized ACT through increased sales in private outlets. Central to this approach is the Affordable Medicines Facility–malaria (AMFm), a mechanism that subsidizes the price of ACT medicines at the producer level, in order to reduce retail prices and promote sales in the private sector. After much debate at the Global Fund to Fight AIDS, Tuberculosis and Malaria, the board of the fund decided in 2008 to host the AMFm, and to pilot it in it in eight locations.[24] The subsidy was offered to buyers from the public, private and not-for-profit sectors. In 2010, an evaluation of the pilots was commissioned in order to provide evidence to enable the Global Fund board to decide the future of the AMFm.

The evaluation offered some useful lessons that will inform future strategies to scale-up malaria treatment. However, it also revealed shortcomings in the pilots that should be recognized. Moreover, the rapidly changing environment for malaria since the inception of the AMFm deserves serious consideration.

This paper explores the rationale and implementation (successes and problems) of the AMFm in the context of the changing malaria landscape. It also examines the current evidence of the performance of various treatment providers. It makes recommendations for the future of the AMFm and for scaling-up malaria treatment more broadly.

2 THE AMFm: RATIONALE AND HISTORY

The AMFm emerged from the 'Saving Lives, Buying Time' study, published in 2004 by the US Institute of Medicine (IoM), and funded by the Bill & Melinda Gates Foundation. The study was conducted at a time when:

- The estimated incidence of malaria was very high, as was the death rate. The global incidence of the disease in 2002 (published 2005) was estimated at 515 million cases and 1.82 million people were estimated to have died of malaria in 2004;[25]
- Malaria was treated presumptively, on the basis of the patient displaying symptoms of fever, without confirmed diagnosis;
- There was a risk that increased use of oral artemisinin monotherapy (AMT) would spread resistance to artemisinin, which would have rendered all currently available antimalarial treatment useless;
- The only ACT medicine available on the market as a fixed-dose combination was Coartem, produced by Novartis. As a result of which the company controlled the global market in terms of production and price. The World Health Organization (WHO) was able to negotiate a special price with Novartis, to provide the medicine at cost to malaria-endemic countries, which led to a rapid increase in prescription of ACT in the public sector. [26]

The concept of the AMFm that emerged from the study was based on the view that people sought treatment in the private sector where ACT was unaffordable, thus encouraging sales of the cheaper AMT, which in turn increased the risk of resistance developing. Given the urgency of reducing the number of deaths from malaria, and delaying the development of resistance, investing in creating viable public health systems to reach rural and remote areas was considered impractical.

The study recommended an annual $300–500m subsidy of ACT – covering the entire global market – in order to achieve end-user prices in the range of $0.10–0.20 per treatment. This price was meant to be similar to the price of chloroquine, a cheap anti-malarial medicine that was rendered useless against *Falciparum* malaria (the main strain in sub-Saharan Africa) partly due to patients not completing their full course of treatment.[27] The idea was that decreasing the price via a global subsidy would increase the use of ACT, thus 'saving lives', and decrease the use of AMT, thus 'buying time' in terms of delaying the development of artemisinin resistance.

After the publication of the IoM report in 2004, the World Bank commissioned studies into the feasibility of a global ACT subsidy, as part of the Roll Back Malaria (RBM) Partnership, which adopted the idea that later became the AMFm. The studies were funded by a $4m grant from the Gates Foundation.[28] The World Bank maintained its support for the subsidy by lending staff to manage the AMFm at the Global Fund.

As the RBM Partnership is not a funding agency, it asked the Global Fund to host the AMFm. Some Global Fund board members, including the governments of the US, Japan and Canada, as well as the Developed Countries NGOs, raised a number of concerns about the AMFm proposal, including the following:

1. **The requirement to pay for treatment** would have a negative impact on access by the poorest people. Evidence shows that paying for health care leads to delays in seeking treatment, or even going without it, with women most likely to be excluded.
2. **The informal private sector does not have the ability or incentive to provide correct diagnosis and treatment.** The concept of the private sector as applied to the sale of medicines in developing countries may be misleading. It includes not only pharmacies, but also unregulated informal private sellers, such as street vendors, market stall-holders and grocers – people without medical qualifications who are motivated by commercial interest, not public health outcomes. They lack the incentive and ability to deliver correct diagnosis and treatment for malaria.
3. **Many fevers are not malaria, so an informal private sector provider is the wrong place for sick people to go.** Studies in the 1990s showed that malaria was responsible of 40 per cent of fever cases in children in sub-Saharan Africa, meaning that the majority of fevers – 60 per cent – were not due to malaria.[29] Moreover, malaria cases have been decreasing in recent years. This makes it even more critical that children with a fever are diagnosed and treated appropriately – for malaria or non-malarial fevers. The informal private sector is not qualified to do so. The fact that many people currently get their malaria medicines from informal private providers is not a sound public health approach to be built on, but a dangerous outcome of a lack of investment in public provision. Not only is it dangerous for people to be given the wrong medicines, this may also contribute to worsening drug resistance. Thus increased sale of ACT is not an indicator of better health outcomes. At the time of negotiating a draft decision for the Global Fund board, NGOs raised concerns about the Global Fund's responsibility for the potential death of children from pneumonia if their parents had paid for the ACT the children did not need. However, this concern was not recognised by some other board members.
4. **The AMFm has the potential to increase resistance to malaria drugs.** Far from delaying the development of resistance, the uncontrolled sale of subsidised ACT could lead to a similar outcome as that of chloroquine treatment against *Falciparum* malaria (as detailed above).
5. **Decreasing the ex-factory price does not need a subsidy**. The AMFm used normal market mechanisms to achieve price reductions by negotiating with companies, using pooled procurement, and through encouraging generic competition.
6. **Decreasing the final price to patients can also be achieved via donor funding**. Countries receive ACT free as part of grants from donors such as the Global Fund and the US President's Malaria

> Initiative (PMI). Developing countries governments are able to use donor funding to purchase ACT for both public and private sectors, and therefore there is no need for a new subsidy.[30]

Moreover, it is unclear why AMFm is necessary. Governments are able to use donor funding, for instance from the Global Fund and the PMI, to purchase ACT for both the public and private sectors, leaving no need for a new subsidy.

The Global Fund is a demand-driven mechanism with a principle of recipient country ownership, yet the AMFm was not established as a result of recipient countries demanding delivery of ACT by the private sector.

The problem of finding funding for the AMFm was solved mainly through UNITAID, the international drug purchasing facility, which contributed the majority of the subsidy. The NGO delegation to UNITAID raised several concerns, including:

- The importance of making the price of ACT globally affordable beyond the pilot countries;
- The limited value of the AMFm to the public sector where the end-user price is already zero because ACT is provided free of charge;
- Increased market share of ACT compared to ineffective malaria medicines does not equate to an increase in ACT use for confirmed malaria cases in vulnerable populations.

The Developed Countries NGOs continued to raise these concerns with board members of both the Global Fund and UNITAID, as well as in the media.[31] It was only in 2010, after the WHO published guidelines for malaria treatment that emphasized the importance of diagnosis before prescribing ACT, that the issue of diagnosis was taken seriously by AMFm supporters such as RBM.[32] Yet the debate on the provision of rapid diagnostic tests (RDTs) is following the same path as the AMFm: instead of looking at the evidence of the correct use of RDTs by various providers, the discussion in the malaria community has focused on how to increase RDT use by the private sector.

THE EVALUATION OF THE PILOTS

In 2010, the Global Fund commissioned an evaluation of the pilot programme to enable it to decide whether to continue, scale-up, or terminate the AMFm.[33] The evaluation was supposed to provide evidence on:

> (i) increased ACT affordability, (ii) increased ACT availability, (iii) increased ACT use, including among vulnerable groups, and (iv) “crowding out” oral artemisinin monotherapies, chloroquine and sulfadoxine-pyrimethamine by gaining market share. The Board further clarifies that it will consider evidence that the AMFm will achieve these four objectives more cost-effectively than other financing models that aim to achieve similar objectives solely or

principally through the expansion of public sector services (i.e., public health facilities and community health workers only).[34]

Given that the drugs were being subsidized at source, it is reasonable to expect an increase in availability and market share, and a decrease in price. However, the key measure of any such treatment initiative must be increased provision to those who actually need the treatment. Yet the AMFm secretariat decided not to systematically evaluate increased utilisation of ACT, including among vulnerable groups such as children and those in rural and remote areas, claiming that this would be too costly in terms of time and resources. The secretariat also commissioned a study which concluded that measuring cost-effectiveness was not feasible.[35]

Nevertheless, even before the publication of the pilot phase evaluation, proponents of the AMFm hailed it as a success on grounds that it increased availability and market share and decreased the private sector price of ACT drugs.[36]

The evaluation, in fact, showed mixed results. It revealed many lessons that should be absorbed before further decisions are taken. The major achievement was the ex-factory price reduction that was achieved through negotiation with companies, generic competition, and security of funding to pharmaceutical companies. Price reduction to the end user occurred in some pilots and only in the private sector. Some problems appear to be inherent to the AMFm design and were predicted by critics, while others are related to the changing malaria landscape.

The evaluation showed:

1. The AMFm performance was mixed, which shows that a single global subsidy model as recommended by the 2004 study does not fit all needs. Country context and experience of malaria control are critical to treatment strategy design;
2. Increased market share and availability of ACT drugs. However, there is no evidence that this increase was reflected in increased use of the medicine by vulnerable groups or increased treatment of actual malaria. Therefore, it is not possible to state with certainty how many lives were ‘saved’ by the AMFm;
3. The AMFm had hardly any impact in terms of the crowding out AMT because the level of these medicines in the market was already low due to regulatory interventions. Thus the second aim of AMFm – ‘buying time’ – was not relevant;
4. The concerns about diagnosis and treatment of non-malarial fevers in the informal private sector remained, given that ACT was sold without confirmed diagnosis;
5. Little evidence as to whether AMFm benefited vulnerable populations, such as poor patients and children;
6. That cost-effectiveness is difficult to determine given the lack of data on total costs and inadequate data on effectiveness (judged as treating confirmed malaria cases in vulnerable populations).

These issues are discussed in detail below.

COUNTRY CONTEXT AND MIXED RESULTS

The unique feature of the AMFm is the principle of a single global subsidy that would increase treatment with quality ACT, and crowd out AMT and other ineffective drugs. Yet the results, from across the evaluation's parameters, were mixed, as the table below shows.

Table 1: Achievements across the evaluation parameters as per the Global Fund Independent Evaluation of AMFm Phase 1

Parameter	*Pilot countries/territories that achieved the parameter*	*Pilot countries/territories that did not achieve the parameter*
Availability	5	3
Price of all quality ACT	5	3
Price of ACT carrying AMFm logo	3	5
Market share	4	4
Crowding out of AMT	AMT use was very low before AMFm was implemented	
Use of ACT	Not measured	

Source: AMFm Independent Evaluation Team (2012) 'Independent Evaluation of Phase 1 of the Affordable Medicines Facility-malaria (AMFm), Multi-Country Independent Evaluation Report: Final Report', Calverton, Maryland and London: ICF International and London School of Hygiene and Tropical Medicine

The AMFm was not conceived in terms of evidence of what works, in particular in a country context. For example, Zanzibar is on its way to eliminating malaria and only a small number of cases remain (2,338 cases in 2010). The public sector and a network of CHWs already provide access to RDTs and ACT. Thus, there is no need to introduce more ACT through private sector outlets.

In Madagascar and Niger, impact on private sector market share was slow because the sale of malaria medicines is dominated by market stall-holders, general stores, open markets, and street vendors. Although these facts were known before the start of the AMFm pilot programme, no strategy was developed to address how to distribute ACT safely through the largely unregulated informal outlets.

Tanzania has a national strategy based on a mixture of public health services, CHWs and regulated drug shops. Other countries beyond those in the pilot scheme, such as Senegal and Ethiopia, have achieved a decrease in malaria incidence, morbidity and mortality through the public sector.[37]

Availability

The original AMFm proposal for funding offered it to both the public and private sectors. However, in reality the public sector share was less than half that of the private sector, which dominated orders in Ghana,

Madagascar, Nigeria, Tanzania, and Zanzibar. Only in Uganda and Niger did orders from the public sector exceed those from the private sector, while equal quantities were ordered by both sectors in Kenya.[38]

Availability of ACT increased by a modest level in the public sector in countries that focused on this sector, such as Kenya, Niger, and to some extent Nigeria and Madagascar. However, the public sector in Ghana, Tanzania, and Uganda suffered periodic stock-outs, especially of children's medicines.[39] The evaluation attributes the slowness of ordering ACT in the public sector to bureaucratic and inefficient procurement – a situation that already existed at the start of AMFm, yet there were no strategies developed to speed up procurements or to stop stock-outs.

The AMFm evaluation states that the biggest success was in the private sector. Yet it does not address the concerns raised by Global Fund board members: that increased sales of ACT is not a sufficient indicator of AMFm success. Evidence is required that what was being treated was confirmed malaria and that vulnerable populations were being served.

Table 2 indicates the WHO's estimate of malaria cases in the pilot countries in 2010 and the total orders for the same pilot countries in 2011. Although the estimates are based on reported cases in the public sector, the figures indicate of the disparities between the number of purchased treatment courses and the estimated cases of malaria. If orders were based on clinical needs, then the 2010 figures should have served as a guide for the 2011 ACT purchasing orders.

Table 2: Estimated malaria cases in 2010 and AMFm treatment orders in 2011

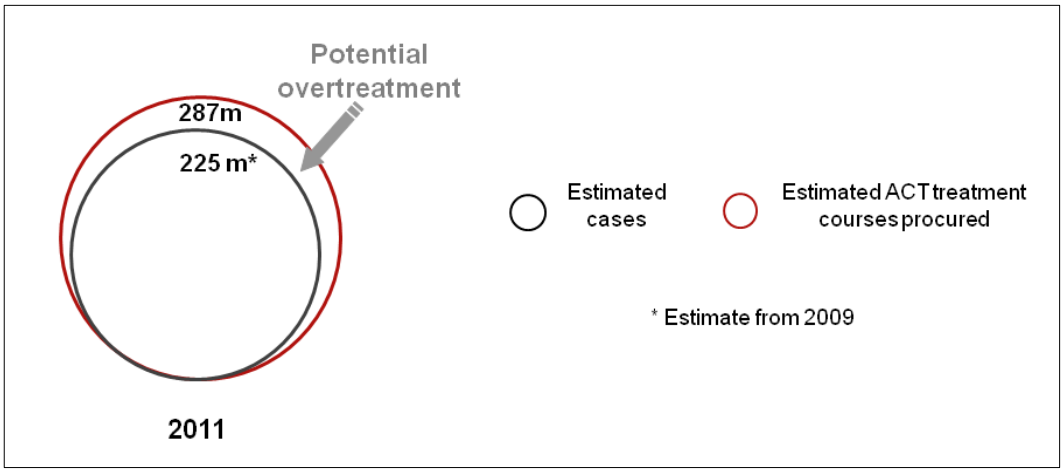
Country	*Number of malaria cases (2010)*	*AMFm orders in 2011 (ACT delivered by AMFm)*
Ghana	2,642,221	24,673,726
Kenya	4,585,712	28,456,638
Madagascar	202,450	1,688,178
Niger	620,058	2,225,120
Nigeria	3,873,463	57,261,301
Tanzania-main land	8,748,012	13,039,620
Uganda	11,084,045	28,226,700
Zanzibar	2,338	241,075
Total	**31,758,299**	**155,812,358**

Sources:
Number of malaria cases (2010)**:** WHO (2011) 'World Malaria Report', Geneva: WHO
AMFm orders in 2011: AMFm Independent Evaluation Team (2012) 'Independent Evaluation of Phase 1 of the Affordable Medicines Facility-malaria (AMFm), Multi-Country Independent Evaluation Report: Final Report', Calverton, Maryland and London: ICF International and London School of Hygiene and Tropical Medicine

Orders were not based on clinical needs. For example orders from Ghana amounted to just over one treatment course for every person in the country. It is unclear if this assumes that every Ghanaian will have an attack of malaria in 2011. It should be borne in mind too that many

countries have other sources of ACT drugs, through grants from the Global Fund, PMI and other donors. For example in 2011, PMI distributed 114,759 treatments in Ghana.[40] The total ACT treatments purchased by AMFm for the 8 pilots was 155,812,358, nearly five times the estimated number of malaria cases in 2010 in those countries.[41]

Figure 1: ACT Treatments in 2011 – Purchasing exceeding need



Sources:
Graphic: UNITAID
Overall cases: Figure taken from WHO (2010) 'World Malaria Report', http://www.who.int/malaria/world_malaria_report_2010/en/index.html
Number of ACT treatment courses: This represents demand for ACT treatment courses, from Demand Forecast for Artemisinin-based Combination Therapies (ACTs) in 2011-2012, UNITAID Forecasting Service, http://www.unitaid.eu/actforecasting

The uncontrolled scale of orders in 2011 led to a crisis in ACT drug supply that required urgent action by key donors. The AMFm secretariat and the Global Fund were forced to put a limit on the flood of orders from private sector wholesalers.

The ACT Crisis

As early as April 2009 the US government warned that 'in the event that manufacturers run short of ACT, this could lead to the situation where the AMFm is pouring drugs into the private sector (where we know a much higher percentage of ACTs will be used for non-malarial fevers) at the same time that public-sector clinics are stocking-out'. It urgently requested that the Secretariat 'develop a plan for the global monitoring of ACT procurements under the AMFm, and establish a system that will enable them to intervene with manufacturers to prioritize procurements to the public sector ahead of the private sector, in the event of a product shortfall.'[42]

However, this was not adopted by the AMFm secretariat.

In 2011, the predicted crisis in the global ACT drug market loomed, driven by the large number of orders from wholesalers in the AMFm pilot countries, which were absorbing drug companies' manufacturing capacity.

Features of the AMFm approach had led to an ACT drug shortage. Orders were based not on clinical need but rather on commercial interest. For example, in Zanzibar, with a very low level of malaria cases and a functioning system of provision via the public sector and CHWs, the private

sector ordered 240,000 treatments – far more than was needed. It was left to pharmaceutical companies to decide whether a country needed a particular order or not. The majority of private sector orders were for adult treatments, even though the majority of malaria cases, and fatalities, are among children.[43] ACT drugs were being ordered primarily – not for the children who needed them – but for the adults who could afford them.

The ordering of excessive quantities of adult treatments meant that the active ingredients were being wasted, all the more so as adult treatments use more ingredients than do child treatments. This inevitably led to a decrease in the companies' capacity to produce child treatments.

In the rush for implementation of the pilots, the AMFm did not oblige providers to use diagnostic tests. This was at odds with the new WHO guidelines on malaria treatment. It is likely that there was excessive use of ACT to treat patients with all kinds of fevers, rather than treatment being given on the basis of diagnosed malaria.

After slow uptake during the first year (2010), the explosion of orders during the first half of 2011 disrupted the market, contributing to an increase in the price of the raw materials.[44] It also led to an overspend resulting in the AMFm having to request an additional $124m from UNITAID, the UK Department for International Development (DFID) and the Canadian Government. The UNITAID board failed to seriously question the mismanagement of commercial orders.[45]

An urgent meeting of key stakeholders including the Global Fund, the AMFm secretariat, UNITAID, WHO, RBM, and PMI forced the AMFm to apply 'demand levers', evaluating orders on the basis of criteria including the ratio of cumulative orders to estimated demand and the ratio of paediatric to adult doses.[46] It is surprising that such common-sense criteria were not applied from the beginning. Instead, the system of unchecked orders was treated as a great success, as if the level of orders represented real clinical need.

Price

The AMFm succeeded in decreasing the price of ex-factory ACT drugs for wholesalers, partly by negotiating with drug companies (taking the price already offered to the public sector as a benchmark) and partly through securing demand and funding for pharmaceutical companies. By 2010, a number of Indian generic ACT drugs had entered the market, increasing competition and leading to further price reductions.[47]

The decrease in price for end users varied between countries and providers. Among the AMFm pilots, prices decreased to below $1 per treatment in retail outlets in Kenya and Tanzania, but remained above a dollar in five others. In Madagascar, the ACT price actually increased to more than that of the already existing schemes of subsidized ACT. Price is important given the high level of poverty in the pilot countries and the fact that in all of them the price of non-ACT drugs was generally less than $1 per treatment. None of the pilot countries achieved the price reduction aimed for by the AMFm, from $6–10 to $0.20–0.50 per treatment.[48]

However, there is some anecdotal evidence to show that the price decreases that did occur actually encouraged inappropriate use of ACT drugs by patients able to pay, as a treatment for illnesses other than malaria.[49]

The evaluation showed no improvement in prices in the public sector in the majority of countries because ACT drugs were already free.

In sum, the AMFm did decrease private sector retail prices in most pilot countries, but not to the level of non-ACT drugs, casting doubt on its ability to increase poor people's access to ACT. Moreover, despite the decrease in the private sector retail price in pilot countries, the global price of ACT drugs increased (see below).

Crowding out ineffective medicines

The aim of crowding out ineffective malaria treatments and AMT has been a pillar of the AMFm from the beginning. But the AMFm pilots had hardly any effect on AMT drugs because their availability on the market was already very low. During the debates on AMFm in 2008–2009, some Global Fund board members, including the Developed Countries NGOs, called for a regulatory approach. However, AMFm's proponents argued that the public sector was weak and that there was no time to wait for regulations to be brought into force. Yet regulation is exactly what occurred, as both poorer and better-off countries banned importation and sale of AMT in public and private sectors, and implemented effective control measures. The WHO also played an important role in persuading drug companies to stop manufacturing and selling AMT. As a result the AMFm aim of 'buying time' ceased to be relevant. Instead the evidence shows that countries needed to expand their enforcement of the drug regulations.

Apart from AMT, AMFm did not replace the ineffective drugs used to treat *Falciparum* malaria; chloroquine and sulfadoxine-pyrimethamine remained widely available in nearly almost sites.[50] The AMFm pilots, then, did not crowd out non-ACT products in the public sector because this had already been achieved. In the private sector, the AMFm succeeded in getting a bigger market share for ACT, but this did not reach the level attained by the public sector.

Reaching target populations: Poor people and children

This issue has been of particular concern for some Global Fund board members. An early report from the RBM Task Force on AMFm pointed out its inability to reach poor people and concluded that 'Unfortunately, there are significant constraints for interventions to reach these populations cost-effectively and at scale'.[51] Yet ideas to increase access via routes other than the private sector, such as distributing ACT free to poor people or allocating a specific proportion of the subsidy to expand free public sector health care, were not seriously considered. It was left to countries to decide how to reach poor people.

Access to and use of ACT by poor people for cases of confirmed malaria, are an important issue. A large proportion of the population in malaria endemic countries, including those enrolled in the pilots, live below the poverty line.[52] Much evidence exists that the need to pay for health care, including medicines, acts as a deterrent to poor people seeking treatment, especially women. When suffering from malaria, poor people may be able to afford only incomplete courses of malaria treatment, failing to cure the disease and perhaps contributing to the emergence of resistance to the only remaining effective treatment for malaria.

Malaria disproportionately affects children. According to the WHO, 86 per cent of malaria deaths occur in children under 5 years of age.[53] Yet the majority of ACT medicines purchased by the private sector, before the Global Fund application of 'levers' in late-2011, went to adults – missing the main target for accessing treatment.

In Ghana, the public sector ran out of stock and had to buy AMFm-funded medicines from the private sector. The AMFm secretariat hailed this as a success for AMFm despite the fact that the purchased ACT drugs were for adults, while the need was for children's medicines. As a result, hospitals were forced to buy locally produced syrups that were not quality-assured. Eventually PMI intervened to deliver quality-assured paediatric formulations.[54] PMI purchased 14.8 million treatments for the public sector in AMFm countries[55] in 2011 and 27.2 million treatments for these countries in 2012.[56]

Dealing with non-malarial fevers

Even as far back as 1991 evidence existed that 'all fever is not malaria'. It was estimated then that malaria was responsible for just 40 per cent of all the fevers in Africa, leaving 60 per cent at risk of being wrongly diagnosed.[57]

Pneumonia is the number one killer of children worldwide and a main killer of children in Africa. Moreover, a high percentage of children suffer both diseases at the same time.[58] Treating fevers as malaria in the age of RDTs, risks missing the real cause of fever. As the use of RDTs by public sector health services and CHWs increases, the true number of malaria cases in particular countries will be revealed. It is likely that the use of ACT will decrease, as has already happened in Senegal. Between 2007 and 2009 the use of RDTs in Senegal increased from 6.2 per cent to 86 per cent. As a result of testing before treatment, the prescription of ACT decreased from 67.7 per cent to 31.5 per cent of malaria-like febrile illness during the same period.[59]

There is a concern that health workers are still overprescribing ACT for non-malarial fevers, despite negative tests. Encouragingly, recent studies have shown a decrease in this behaviour, with CHWs in particular adhering to the test results.[60]

Given the high prevalence of non-malarial fevers, it makes clinical and economic sense to treat malaria within a broad public health approach.

This means focusing on training and supervision of health workers, especially CHWs, who are able to diagnose and treat common fevers.

Cost and sustainability

The AMFm facility costed the subsidizing of ACT at $390m. In addition, the Global Fund provided $127m for supporting interventions, such as media campaigns, by reprogramming grants meant for the public sector. These financial inputs cover one-and-a-half years of implementation in the eight pilots.[61] However, the figures do not include the costs borne by other donors in preparation for and during AMFm implementation. For example, the UK spent £537,209 to 'develop a policy framework to implement AMFm'.[62] The William J. Clinton Foundation provided technical assistance to implementing countries and for research related to the AMFm that was paid for by other donors, such as the Gates Foundation.[63]

It is important to add together all the costs, irrespective of the donor, in order to assess the cost-effectiveness of the AMFm pilots, and the potential cost, and hence cost-effectiveness and sustainability, of any future AMFm activities or any similar subsidy to RDTs. It is questionable that donors will maintain such a high level of funding for the AMFm without knowing its true cost-effectiveness, especially in comparison with other approaches.

3 APPROPRIATENESS OF AMFm TO THE CHANGING MALARIA LANDSCAPE

When the Global Fund decided to host an AMFm pilot project in 2008, the malaria landscape was already changing rapidly. These changes have continued, so that now a reassessment of the appropriateness of AMFm in the current circumstances is needed. The key changes have been:

- **Malaria incidence and mortality are decreasing globally**, including in Africa, thanks to the scaling-up of preventive measures, such as the use of bed nets and indoor spraying with insecticides. As a result, the likelihood that a child with a fever has malaria is lower than was believed to be the case in 2004.
- **RDTs have become a standard tool for diagnosis**, especially since the introduction of the WHO guideline that ACT should be prescribed only for positive tests. Presumptive treatment is no longer acceptable because it risks incorrect treatment of other fevers, endangers patients' lives, and wastes household, national, and donor resources on useless treatment. RDTs have become increasingly available in public health facilities and via CHWs, with annual sales reaching more than 50 million units in 2010.[64]
- **More generic medicines** have entered the market. Since 2008, three Indian generic drug companies have had products prequalified (quality tested and approved) by the WHO and a new fixed dose combination (ASAQ) is available.[65] Generic competition and the availability of secure funding to pharmaceutical companies have proved to be effective mechanisms for price reduction. Moreover, the potential of **synthetic artemisinin** to reduce production cost, and hence the price of ACT, is expected to be felt in the near future.
- The **percentage of malaria being treated with AMT** in both the public and private sectors has dropped dramatically as a result of countries implementing strong regulatory procedures to ban these drugs,[66] as well as the role played by WHO to persuade companies not to produce these drugs.
- The difficulties of regular supply of the ***Artemisia*** **plant (the active ingredient for the artemisinin part of ACT)**, which were not fully recognized, or at least were not met with appropriate solutions at the outset of the AMFm pilots, still persist. However, recently there have been more efforts to forecast demand, especially by UNITAID.[67] Rational use of ACT is an important factor in stabilizing the demand for, and hence supply of, active ingredients.

These changes pose fundamental challenges to the core rationale of the AMFm as a mechanism for 'saving lives and buying time'. In contrast, there is increasing evidence of the effectiveness of the public sector and CHWs in delivering malaria treatment.

4 THE EVIDENCE OF PERFORMANCE OF PROVIDERS OF MALARIA TREATMENT

Plans for the AMFm in 2004 were based on the assumption that people in sub-Saharan Africa relied on the private sector for accessing health care, and that this was therefore the best channel through which to expand provision of ACT. However, new data suggests something different. Studies have shown that there are essential requirements for the delivery of correct diagnosis and treatment of malaria and other fevers. These are:

- Adequate and correct knowledge by the health service provider of diagnostics, malaria treatment, and when to refer severe cases;
- Adequate knowledge of non-malarial fevers, and how to diagnose and treat them;
- Correct behaviour from the provider, especially in terms of adhering to treatment guidelines, ceasing to use ineffective and substandard medicines, and advising patients and carers on adherence to the treatment course;
- An uninterrupted supply of RDTs, ACT, and medicines for other fevers, e.g. antibiotics relevant to specific contexts and diseases;
- Provision of care in the community so that people, especially women, do not have to face the cost of transport to reach a provider;
- Free consultations, diagnostics, and medicines, which enable poor people and other vulnerable groups to benefit from effective treatments.

In order to implement these requirements in any country, governments and donors must invest in the following, irrespective of the actual provider:

- Adequate training on the above aspects of the diagnosis and treatment of malaria and other fevers;
- Adequate and continuous supervision of the provider by professional health workers;
- A functioning drug supply system;
- Support for providers in the community and an adequate system of referral of severe cases;
- Adequate funding to perform the aforementioned requirements.

The question for policy makers is: what are the safest and most cost-effective routes that can deliver effective diagnosis and treatment of malaria and non-malarial fevers?

THE PRIVATE SECTOR: ADVANTAGES AND DANGERS

There is no doubt that the private sector scores highly on its ability to ensure uninterrupted supplies of ACT drugs – as long as wholesalers and retail outlets can make adequate profits and the global market is favourable. Private retailers, such as general stores and market stall-holders, exist in most villages and remote areas and have the advantage of being close to patients, saving them the cost of transport. Moreover, informal private providers generally charge for medicines only, without additional consultation fees. However, they have neither the training nor supervision needed to prescribe safely – especially for non-malarial fevers.

Pharmacies and regulated drug shops tend to have better-educated staff than the informal sector, with some training. However, formal private providers are usually located in, or close to, cities and towns and therefore are not available to the majority of the population in remote rural areas.

There are specific risks related to delivering RDTs and ACT via the private sector, particularly the informal private sector:

- The risk of prescribing ACT for non-malarial fevers. This risk is high due to patient demand when a test has already been paid for, and also because the extra income from ACT sales acts as a direct incentive to sellers. Customers may demand malaria treatment even when they have had a negative test result because they may not accept paying for the test and then not obtaining any treatment;
- The risk of failing to diagnose, and thus to treat, non-malarial fevers. While a trained pharmacist may be able to diagnose and prescribe treatment for pneumonia, the temptation of prescribing newer and more expensive antibiotics risk increased resistance, as could the irrational sale of antibiotics by shopkeepers and other informal sellers;
- The risk of informal providers failing to take account of the high percentage of symptom overlap in children who have both malaria and pneumonia and need appropriate treatment for both;[68]
- The risk of poor people, especially children, being excluded. A recent study found that ACT drugs were more likely to be available in shops near towns and were used more by higher socio-economic groups.[69]

With finite financial resources available, and public health at stake, these concerns cast doubt on the continuation of such malaria treatment programmes.

THE NEGLECTED PUBLIC SECTOR

Public health services do not function well in many countries. Remote areas lack health facilities, and people often have to travel a long way to access vital health services. In 2011, the WHO estimated that there was

a gap of 1.5 million trained health workers in Africa.[70] Drug procurement and supply chains suffer from a chronic lack of investment, leading to delays in medicines reaching distant facilities and problems of expired drugs and stock-outs. Delays in grant disbursement by donors, such as the Global Fund, exacerbate these problems.

Yet such problems are not inherent to the public sector. Some countries have managed to overcome these difficulties and have succeeded in controlling malaria. Despite years of conflict, Sri Lanka has succeeded in controlling malaria through massive distribution of insecticide-impregnated bed nets, indoor spraying, and free diagnostics and ACT.[71]

Rwanda also has an impressive record, having achieved nationwide distribution of long-lasting insecticide-treated nets (LLINs) and ACT in the space of only 60 days in 2006. This action resulted in a sharp decline in the number of malaria cases.[72] A study in Rwanda and Ethiopia concluded that 'the combination of mass distribution of LLINs to all children under 5, or all households, and nationwide distribution of ACT in the public sector was associated with substantial decline of in-patient malaria cases and deaths'.[73]

Many of the countries that have succeeded in scaling-up diagnosis and treatment, such as Ethiopia and Zambia, have done so via a combination of public sector facilities and the deployment of trained CHWs. The public sector has shown it can provide basic services, such as childhood immunization. With the right investment, it should be able to do the same for medicines to treat malaria and other fevers.

THE FORGOTTEN COMMUNITY HEALTH WORKERS

CHWs play an important role in the provision of health care, especially in rural and remote areas.[74] Being members of their communities, CHWs have a number of advantages; in particular they have insights into the beliefs, culture and socio-economic status of their patients. Because they live in the same community, they are flexible, and have no transport costs associated with their services. Usually CHWs are women, which makes them more understanding of patients' and carers' needs, given that the main groups affected by malaria are children and pregnant women. In most cases they offer free services and free medicines. Studies have shown higher utilization of CHWs in remote areas and small villages, and by poor and very poor people.[75]

Evidence has shown that CHWs retain and use knowledge, adhere to treatment guidelines, and that they can perform RDTs and follow the test results.[76] When trained, CHWs are able to treat non-malarial fevers and even manage small stocks of medicines. As a result, CHWs offer a good basis for scaling-up diagnosis and treatment of malaria, as well as non-malarial fevers, as long as they are backed up with the right support and training.

5 CONCLUSIONS AND RECOMMENDATIONS

The progress in malaria control has highlighted the importance of correct diagnosis and treatment, not only of malaria but of other common fevers. It has also highlighted the important role that the public sector can play – through regulation – in enhancing the use of effective medicines, and removing dangerous drugs from circulation, as when the WHO persuaded drug companies to stop manufacturing and selling AMT. These measures have contributed to a decrease in the risk of artemisinin-resistant strains of malaria developing as a result of the use of AMT.

The scaling-up of correct diagnosis and treatment will require investment in adequate training and continuous supervision, irrespective of the provider. There are no short cuts.

Policy makers must choose between three options to scale-up diagnosis and treatment: through the public sector, with its problems of lack of personnel, inadequate supply chains, and lack of facilities in remote areas; or through the private sector with its inability to address public health needs, lack of appropriate training and supervision, and a tendency to exclude the poorest people. The third option is to scale-up through the use of CHWs, while strengthening the public sector.

Donors have favoured the second route, through the AMFm, focusing on the private sector, despite the shortcomings highlighted in the evaluation of the AMFm pilots.

The AMFm is a global subsidy mechanism, whose stated aim is ‘saving lives and buying time’. The main achievements of the AMFm pilot scheme have been increased availability and decreased prices of ACT drugs in the private sector, but these do not necessarily equate to an increase in their use by those who actually have malaria, in particular children and poor people, and therefore it is hard to claim with any confidence that AMFm ‘saves lives’. Moreover, the AMFm was not needed in order to ‘buy time’, since use of AMT, which had threatened to give rise to artemisinin-resistant strains of malaria, had already fallen to a very low level by the time of its introduction, as a result of decisive action by governments. Moreover, the evaluation of the eight pilots produced mixed results, showing that a ‘one-size-fits-all’ approach to combating malaria does not work.

For the most part, the concerns that NGOs and others raised at the inception of the AMFm remain.

Policy makers must weigh the evidence and choose where the best investment is to be made to combat malaria and achieve other public health outcomes. **There are no cheap options.** Whoever provides

treatment must be adequately trained and supervised, meaning that any investment should be based on a thorough analysis of which model would be:

1. Most cost-effective in terms of public health outcomes (correct diagnosis and treatment of malaria and non-malarial fever), with the right training and supervision;
2. Based in the community, thus saving patients the time and expense of travel, and with sufficient knowledge of the community to provide a user-friendly service at flexible times;
3. Inclusive of children and pregnant women, and especially of poor people and those in rural and remote areas, providing them with free diagnosis and treatment;
4. Responsive to women's needs, given that the majority of carers are mothers and that malaria disproportionately affects pregnant women and children.

RECOMMENDATIONS

For the AMFm:

- The Global Fund should take a decision at their November board meeting to cease hosting the AMFm;
- UNITAID and the UK Department for International Development (the AMFm's main funders) should discontinue funding beyond current commitments (the end of 2012);
- If pilot countries wish to continue providing ACT via the private sector, they should do so through normal Global Fund or other donor grants.

For scaling-up malaria treatment:

- **Donors should invest in a public–public partnership between community health workers and primary health care facilities**, with an enhanced emphasis on training and supervision. This approach combines the benefits of public sector and community approaches, while avoiding the risk to public health entailed by the involvement of the informal private sector. It also enables a public health approach to dealing with the majority of non-malarial fevers. Professional, regulated private sector outlets, such as pharmacies, can plug gaps where they exist – normally in cities and towns. This approach is based on what works. It has already happened in countries including Ethiopia, Zambia, Rwanda, and others.

Malaria continues to be a major killer in many developing countries, with 86 per cent of malaria deaths in 2010 occurring in children under five years old.[77] With so many children's lives on the line, it is imperative that donors and governments base their decisions at the November board meeting of the Global Fund and at the December board meeting of UNITAID on evidence of what works for malaria and other pressing public health needs in developing countries.

NOTES

NB. All URLs last accessed October 2012.

[1] UNDP (2012) 'The Millennium Development Goals Report', New York: United Nations

[2] WHO (2011) 'World Malaria Report 2011', Geneva: WHO, http://www.who.int/malaria/world_malaria_report_2011/en/

[3] K.J. Arrow et al (2004) 'Saving lives, Buying time: Economics of Malaria Drugs in an Age of Resistance', Washington, D.C.: The National Academies Press, http://www.nap.edu/openbook.php?isbn=0309092183

[4] U. Brinkmann and A. Brinkmann (1991) 'Malaria and health in Africa: the present situation and epidemiological trends', *Trop Med Parasitol* 42(3):204–13

[5] The Global Fund, Twentieth Board Meeting, Addis Ababa, Ethiopia, 9–11 November 2009, Decision point 24, http://www.theglobalfund.org/en/board/meetings/twentieth/

[6] H. Lemma et al (2010) 'Deploying artemether-lumefantrine with rapid testing in Ethiopian communities: impact on malaria morbidity, mortality and healthcare resources', *Trop Med Int Health* 15(2):241–50

[7] P. Chanda et al (2011) 'Community case management of malaria using ACT and RDT in two districts in Zambia: achieving high adherence to test results using community health workers', *Malar J.* 9;10:158

[8] The Global Fund (2011) 'Report of the Affordable Medicines Facility - Malaria (AMFm) ad hoc committee', Twenty-Fifth Board Meeting, Accra, Ghana, 21–22 November 2011, http://www.theglobalfund.org/documents/board/25/BM25_16AMFmAdHocCommittee_Report_en/

[9] D. Garmaise (2010) 'More Investment in Health Systems Needed, Global Fund Board Chair Says', Global Fund Newsletter 121, http://www.aidspan.org/gfo_article/more-investment-health-systems-needed-global-fund-board-chair-says

[10] AMFm Independent Evaluation Team (2012) 'Independent Evaluation of Phase 1 of the Affordable Medicines Facility - malaria (AMFm), Multi-Country Independent Evaluation Report: Final Report', Calverton, Maryland and London: ICF International and London School of Hygiene and Tropical Medicine, http://www.theglobalfund.org/en/amfm/independentevaluation/

[11] *Ibid*

[12] WHO (2011) *Op. Cit.*

[13] *Ibid*

[14] WHO (2005) 'World Malaria Report 2005', http://www.rbm.who.int/wmr2005/html/exsummary_en.htm; and R.W. Snow et al (2005) 'The global distribution of clinical episodes of Plasmodium Falciparum malaria', *Nature* 434, 214–17 (10 March 2005)

[15] WHO (2011) *Op. Cit.*

[16] S. Yeung et al (2008) 'Access to artemisinin combination therapy for malaria in remote areas of Cambodia', *Malar J.* 29;7:96

[17] A. Ratsimbasoa et al (2012) 'Management of uncomplicated malaria in febrile under five-year-old children by community health workers in Madagascar: reliability of malaria rapid diagnostic tests', Malar J. 2012;11:85; and P. Chanda et al (2011) 'Community case management of malaria using ACT and RDT in two districts in Zambia: achieving high adherence to test results using community health workers', Malar J. 2011;10:158

[18] WHO (2011) *Op. Cit.*

[19] *Ibid.*

[20] UNDP (2012) The Millennium Development Goals Report. United Nations, New York

[21] WHO (2011) *Op. Cit.*

[22] Roll Back Malaria (2008) 'RBM Global malaria action plan', http://www.rbm.who.int/gmap/2-5.html

[23] Roll Back Malaria (2012) 'Sustained Malaria Financing at Heart of Africa's Development Agenda', Press release 23.06.2012, http://www.rbm.who.int/globaladvocacy/pr2012-06-23.html

[24] Pilots took place in Ghana, Kenya, Madagascar, Niger, Nigeria, Uganda, Tanzania, and Zanzibar (while part of Tanzania, it is considered as a separate pilot in this report).

[25] Murray et al (2012) Global malaria mortality between 1980 and 2010: A systematic analysis Lancet; 379: 413–31

[26] WHO (2011) 'Global supply of artemether-lumefantrine before, during, and after the Memorandum of Understanding between WHO and Novartis', WHO, http://www.who.int/malaria/diagnosis_treatment/finance/MoU_termination_report.pdf

[27] K.J. Arrow et al (2004) *Op. Cit.*

[28] A. Jack (2007) 'Attack on malaria drugs subsidy', *The Financial Times*, 11 April, http://www.ft.com/cms/s/0/d10f5d9c-e7c9-11db-8098-000b5df10621.html#axzz29f2EI1WN

[29] U. Brinkmann and A. Brinkmann (1991) 'Malaria and health in Africa: the present situation and epidemiological trends', *Trop Med Parasitol* 42(3):204–13

[30] US President Malaria Initiative (2010) 'Malaria Operational Plan (MOP) Rwanda FY 2011', http://pmi.gov/countries/mops/fy11/rwanda_mop-fy11.pdf

[31] M. Kamal-Yanni (2010) 'Affordable medicines facility for malaria: reasonable or rash?', *The Lancet*, Vol. 375, Issue 9709, pp.121 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60048-7/fulltext

[32] WHO (2010) 'Guidelines for the treatment of malaria, second edition', http://www.who.int/malaria/publications/atoz/9789241547925/en/index.html

[33] AMFm Independent Evaluation Team (2012) Op. Cit.

[34] The Global Fund Twentieth Board Meeting, Addis Ababa, Ethiopia, 9–11 November 2009, Decision point 24, http://www.theglobalfund.org/en/board/meetings/twentieth/

[35] The Global Fund (2011) 'Report of the Affordable Medicines Facility - Malaria (AMFm) ad hoc committee', Twenty-Fifth Board Meeting, Accra, Ghana, 21–22 November 2011, http://www.theglobalfund.org/documents/board/25/BM25_16AMFmAdHocCommittee_Report_en/

[36] The Global Fund (2012) 'Global Fund-led initiative slashes cost of anti-malaria medicines in many African countries', http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-04-25_Global_Fund-led_initiative_slashes_cost_of_anti-Malaria_medicines_in_many_African_countries/

[37] S. Thiam et al (2011) 'Major Reduction in Anti-Malarial Drug Consumption in Senegal after Nation-Wide Introduction of Malaria Rapid Diagnostic Tests', *PLoS One*, 6(4): e18419, http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0018419; and K.I. Barnes et al (2009) 'Impact of the large-scale deployment of artemether/lumefantrine on the malaria disease burden in Africa: case studies of South Africa, Zambia and Ethiopia', *Malar J.* 2009; 8(Suppl 1): S8, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2760243/

[38] AMFm Independent Evaluation Team (2012) *Op. Cit.*

[39] *Ibid*

[40] PMI (2011) 'Fifth Annual Report to Congress', USAID, http://www.pmi.gov/resources/reports/pmi_annual_report11.pdf

[41] *Ibid.*

[42] Email from US government to secretariat and members of the AMFm ad hoc committee, 7 April 2009

[43] RBM-WHO (2011) 'RBM/WHO Round Table on ACT Supply', Geneva, http://www.rollbackmalaria.org/partnership/wg/wg_procurementsupply/docs/RBM-WHO-Round-Table-on-ACT-Supply.pdf

[44] UNITAID, BCG, Clinton Foundation, MIT Zaragoza (2011) 'Global ACT Supply and Demand 2011', Situation Summary and Next Steps Presentation at the RBM/WHO roundtable on ACT supply, Geneva

[45] UNITAID Fifteenth Executive board meeting, December 2011, Resolution 7 'Affordable Medicines Facility – malaria (AMFm) Extension Proposal', http://www.unitaid.eu/images/EB15/R07_EB15_%20Amfm-rev1.pdf

[46] RBM-WHO (2011) *Op. Cit.*

[47] WHO List of Prequalified Medicinal Products, http://apps.who.int/prequal/query/ProductRegistry.aspx?list=ma

[48] The Global Fund (2009) 'Affordable Medicines Facility for Malaria – AMFm: Appendix A - Proposal Template', Funding Proposal to UNITAID, http://www.unitaid.eu/images/operations/malaria/amfm/TGF_Proposal-AMFm.pdf

[49] A. Maxmen (2012) 'Public health: Death at the doorstep', *Nature* 484: 7395, S19–S21, http://www.nature.com/nature/journal/v484/n7395_supp/full/484S19a.html

[50] The Center for Disease Dynamics, Economics & Policy (CDDEP) (2012) 'The future of the Affordable Medicines Facility-Malaria: Will AMFm play on?', Issue Brief, Washington D.C.: CDDEP, http://cddep.org/sites/cddep.org/files/publication_files/amfm_issue_brief.pdf

[51] RBM (2008) 'AMFm: Summary Report of Technical Guidance Provided by the RBM Task Force', Global Fund AMFm Ad Hoc Committee

[52] For example, 49 per cent in Kenya, 68 per cent in Madagascar, 63 per cent in Niger, 55 per cent in Nigeria, and 35 per cent in Uganda.

[53] WHO Global health Observatory, 'Malaria', http://www.who.int/gho/malaria/en/index.html

[54] Personal communication between author and PMI

[55] Ghana, Kenya, Madagascar, Nigeria, and Tanzania.

[56] US President Malaria Initiative (2012) 'AMFm and PMI's Commitment to Global Efforts to Ensure Prompt Malaria Diagnosis and Treatment', PMI, http://www.pmi.gov/news/pressreleases/amfm_stmt.html

[57] U. Brinkmann and A. Brinkmann (1991) *Op. Cit.*

[58] K. Källander, J. Nsungwa-Sabiiti, and S. Peterson (2004) 'Symptom overlap for malaria and pneumonia – policy implications for home management strategies', *Acta Trop.* 2004 Apr; 90(2):211–14

[59] S. Thiam et al (2011) *Op. Cit.*

[60] I.M. Masanja et al (2012) 'Increased use of malaria rapid diagnostic tests improves targeting of anti-malarial treatment in rural Tanzania: implications for nationwide rollout of malaria rapid diagnostic tests', *Malar J*. 2012, 11:221, http://www.malariajournal.com/content/11/1/221

[61] The original estimate by McKinsey was $200-250 for the subsidy, $100m–125m for supporting interventions and $14.4m for a secretariat

[62] DFID 'Affordable Medicines for Malaria Project: Project Details', http://projects.dfid.gov.uk/project.aspx?Project=113955

[63] William J. Clinton Foundation, http://www.gatesfoundation.org/Grants-2009/Pages/William-J-Clinton-Foundation-OPP52790.aspx

[64] WHO (2011) *Op. Cit*., Chapter 6.

[65] WHO List of Prequalified Medicinal Products, http://apps.who.int/prequal/query/ProductRegistry.aspx?list=ma

[66] AMFm Independent Evaluation Team (2012) *Op. Cit.*

[67] http://www.unitaid.eu/actforecasting

[68] K. Källander, J. Nsungwa-Sabiiti, and S. Peterson (2004) *Op. Cit.*

[69] J.M. Cohen et al (2010) 'A pharmacy too far? Equity and spatial distribution of outcomes in the delivery of subsidized artemisinin-based combination therapies through private drug shops', *BMC Health Serv Res*.;10(Suppl 1):S6, http://www.biomedcentral.com/1472-6963/10/S1/S6

[70] WHO (2011) 'Enabling Solutions, Ensuring healthcare', Global Health Workforce Alliance 2011 Annual Report, http://www.who.int/workforcealliance/knowledge/resources/annualreport2011/en/index.html

[71] R.R. Abeyasinghe et al (2012) 'Malaria control and elimination in Sri Lanka: Documenting progress and success factors in a conflict setting', *PLoS One* 7(8):e4316, http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0043162

[72] M. Otten et al (2009) 'Initial evidence of reduction of malaria cases and deaths in Rwanda and Ethiopia due to rapid scale-up of malaria prevention and treatment', *Malar J.*14;8:14, http://www.malariajournal.com/content/8/1/14

[73] *Ibid.*

[74]The Earth Institute (2011) 'One Million Community Health Workers: Technical task force report', The Earth Institute, University of Columbia, http://www.millenniumvillages.org/uploads/ReportPaper/1mCHW_TechnicalTaskForceReport.pdf

[75] J. Kisia et al (2012) 'Factors associated with utilization of community health workers in improving access to malaria treatment among children in Kenya', *Malar J.* 30;11(1):248

[76] Chanda et al (2011) *Op. Cit*.; and Lemma et al (2010) *Op. Cit.*

[77] WHO (2011) *Op. Cit.*

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