



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?

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 UNAIDS 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 USA 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 Ethiopia⁶ 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 ACT 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 2005¹⁴ 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 than 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.

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,
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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,
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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,
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⁹ D. Garmaise (2010) 'More Investment in Health Systems Needed, Global Fund Board Chair Says', Global Fund Newsletter 121, http://www.aidspace.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,
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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. Ratsimbaoa 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.*

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