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In recent years, several constraints have impeded access to effective treatments for malaria due to Plasmodium falciparum. First, the parasite has become increasingly resistant to established cheap drugs, such as chloroquine and sulfadoxine-pyrimethamine. Second, development assistance has been routed largely through public channels, whereas affected individuals seek treatment mostly through the private sector. Finally, new artemisinin-based combination treatments (ACTs), recommended by WHO for uncomplicated falciparum malaria,1 are too expensive for many people who seek treatment in the private sector. These three restrictions have resulted in low coverage of ACTs and persistent use of oral artemisinin monotherapy, thereby increasing the risk of widespread parasite resistance to artemisinin—the only widely effective first-line treatment.

The three constraints noted above have prompted exploration of new approaches to resolve difficulties of low coverage of combination regimens and continued use of inappropriate monotherapy. The Affordable Medicines Facility—malaria (AMFm) is an innovative financing mechanism to expand access to affordable ACTs through the public and private sectors and non-governmental organisations (NGOs) and, crucially, to displace oral artemisinin monotherapies from the market.2, 3AMFm has the potential to transform the way universal access to new malaria drugs and similar technologies is financed. Managed by the Global Fund, it aims to reduce the cost of ACTs sold in the private sector, from up to US$11 per treatment at present to the same price as chloroquine or sulfadoxine-pyrimethamine (about $0—50) and to less than the cost of oral artemisinin monotherapy (about $3—7). Patients who receive malaria treatment through public-sector clinics and not-for-profit services will also benefit from increased access to free or low-cost ACTs.

The origins of AMFm have been described previously,4, 5 and findings of two small pilot projects indicate that its basic design works in practice.6, 7 Here, we present an interim perspective on implementation of AMFm and potential lessons for the architecture of financing universal access to lifesaving health technologies.

The design of AMFm incorporates three elements: (1) price reductions through negotiations with manufacturers of ACTs; (2) a buyer subsidy, via a co-payment at the top of the global supply chain; and (3) support of interventions to promote appropriate use of ACTs.8 The key innovation is the combined approach to reduce prices substantially by negotiation with manufacturers and by global subsidy. This objective entails payment by AMFm of a large part of the post-negotiation price (the co-payment) on behalf of eligible first-line buyers from the public and private sectors and NGOs, who all purchase ACTs directly from the manufacturer.

AMFm has two funding streams. A first co-payment fund of US$216 million—financed by the Bill & Melinda Gates Foundation, the UK Government, and UNITAID—covers the subsidies. A second allocation of US$127 million from the Global Fund finances supporting interventions.

After Global Fund board approval in November, 2009, phase one of AMFm started in mid-2010 and is scheduled to last for 2 years. It will be implemented in eight countries: Cambodia, Ghana, Kenya, Madagascar, Nigeria, Niger, Tanzania, and Uganda. AMFm will provide co-payments for first-line buyers of ACTs in these countries, but it will only co-pay for the purchases of products that meet quality criteria of the Global Fund's quality assurance policy.9AMFm has concluded master supply agreements with six pharmaceutical companies that met its quality criteria for supply of ACTs to first-line buyers, namely: Ajanta Pharma, Cipla, Guilin Pharmaceutical, Ipca Laboratories, Novartis, and Sanofi-Aventis. This achievement is important because, in a departure from previous practices, manufacturers will sell ACTs to first-line buyers from the private sector at the same reduced prices as they sell to public-sector buyers. Manufacturers have agreed to not market oral artemisinin monotherapy. AMFm has set a maximum acceptable price that manufacturers may charge first-line buyers for each formulation pack size. The subsidy is then applied to each quoted price in the form of a fixed co-payment.

Four challenges to implementation of AMFm, which are most directly related to its design, are: (1) passing the subsidy on to patients at the retail level; (2) learning the most effective ways to expand access to diagnostic tests for malaria; (3) reaching poor and remote populations with ACTs;10, 11 and (4) finding the appropriate approach to evaluation and benchmarking of phase one. We examine each of these challenges in turn.

First, the risk with a high-level subsidy is that some of its benefits might be captured by first-line buyers and middlemen. To mitigate this risk, the Global Fund requires every first-line buyer to sign an undertaking to pass on to those further down the supply chain the benefits of the buyer subsidy that they (the first-line buyers) will enjoy. First-line buyers commit to addition of no more than a reasonable margin, defined as the margin they would normally add to other antimalarials bought at prices comparable with the subsidised ACTs. Findings of a pilot study of ACT subsidies in Tanzania showed that the approach worked without price gouging by middlemen.6 Nevertheless, there is no guarantee that every participant in the supply chain will honour all agreements at all times.

The Global Fund has commissioned an AMFm-specific logo that countries are using for branding and marketing of co-paid ACTs. The logo also has a potential benefit of enabling buyers to identify subsidised drugs that should cost substantially less than unsubsidised products.

With respect to the second challenge, in 2009, the Global Fund encouraged applicant countries to include expansion of access to diagnostic tests for malaria as a supporting intervention in their AMFm applications, including operational research to inform wider use in the private sector. These diagnostic tests will not be financed from the co-payment fund for subsidies but from grants for supporting interventions.

WHO updated its guidelines in 2010 for parasitological confirmation of malaria.12 Universal access to diagnostic tests will help restrict use of ACTs to only patients with parasitaemia. A large proportion of presumptive diagnosis and treatment of malaria takes place in the private sector. For example, in the Democratic Republic of Congo, the private sector dominates the market for antimalarials, distributing 85–6% of all drugs of this type. In Nigeria, the private sector accounts for about 95% of all antimalarial

drug distribution.13 In 2006, these two countries alone comprised just over a third of all cases of suspected malaria in the WHO Africa region. Formal public-sector services are unlikely to cover all cases of suspected malaria in the near-to-medium term. Therefore, universal access to diagnostic tests requires that all patients with suspicion of malaria in the private sector be tested by a suitable method. Yet, knowledge is modest of scalable approaches to achieve this goal in the private sector. This phase one implementation provides an opportunity to learn about scalable approaches before a potential global roll-out of AMFm in 2012.

The third challenge relates to the speed at which subsidised ACTs will reach the poorest and most remote populations. Improvement of access in distant locations is the focus of some supporting interventions and operations research in AMFm phase one. The new financing architecture of AMFm can benefit any service delivery model because service delivery organisations will be able to buy ACTs at reduced prices, but any one approach to service delivery is unlikely to work universally and uniformly on a large scale.

The final challenge of implementation relates to evaluation and benchmarking of AMFm phase one. Universal access to effective treatments is a goal of the Roll Back Malaria Partnership,14 but despite official commitments and substantial increases in financing, this objective remains elusive. In 2009, the conclusion of the 5-year evaluation of the Global Fund stated:

This observation could be accounted for by a lag between financial commitments and implementation of activities. However, reports based on more recent data indicate little progress in overall access to ACTs, with price remaining a major barrier to access.13 In Africa, only 14 countries reported distribution of enough ACTs to treat at least 50% of reported malaria cases in the public sector, and only five countries reported allocation of sufficient ACTs to treat all reported cases of malaria in 2008.16Evidence of the success of AMFm phase one, to be ascertained by independent assessment of the pilot projects, will inform a decision by the Global Fund board on the future of AMFm. Endpoint evaluation data will be gathered after about 1 year of implementation. Two complementary approaches could be used, inter alia, to assess success. The first entails measurement of how far AMFm progresses towards achievement of its stated objectives to reduce prices, increase availability of ACTs, gain market share, and augment use of ACTs in view of the period of implementation. The second compares AMFm with other financing platforms that have similar objectives, whether such financing platforms seek to achieve those objectives through the public sector or through several sectors. Such direct comparisons would provide (for the first time and with similar indicators) independent and verifiable comparisons of performance of financing platforms. An obvious comparator is the existing Global Fund malaria grant financing scheme, because if the Global Fund had additional resources without AMFm, such resources would normally be channelled through those grants. Other potential comparators might include non-Global Fund programmes, such as the US President's Malaria Initiative17 and the World Bank's Booster Program for Malaria Control.18 Such comparisons, which make data, methods, and results available in the public domain, would promote a

culture of independent and contestable monitoring and evaluation of performance in an era of tight budgets, with increased emphasis on performance and value for money.19Time is a relevant factor in assessment of the performance of AMFm phase one; the report of the 5-year evaluation of the Global Fund20 is instructive in setting expectations of achievements within the duration of AMFm phase one. Another important principle is to compare like with like. Finally, the scale of comparators is relevant. Unless these factors are taken into consideration, there will be a high risk of conflating a financing mechanism such as AMFm, which benefits all approaches to service delivery, with specific schemes. Comparison of a short-lived proof-of-concept such as AMFm with initiatives that have had much longer periods to mature will be a further risk.

In our view, an appropriate expectation for the short duration of the pilot phase is that the innovative aspects of AMFm are shown to work, in terms of direction of change in price and availability of ACTs and in initial displacement of oral artemisinin monotherapies from the market. These achievements can be assessed at outlets in the public and private sectors and compared with independent evaluations of other financing mechanisms after similar periods of implementation. Expectations of attributable and rapid increases in measures of service delivery at the household level, which are neither new nor unique to AMFm, are inappropriate and unrealistic within the duration of the pilot studies. Crucially, they are incompatible with the key finding of the 5-year evaluation study of the Global Fund in relation to time needed for maturation of new approaches.20In conclusion, available evidence suggests that the traditional approach to development assistance for malaria treatment, which puts most resources through the public sector alone, will not achieve by 2015 Millennium Development Goal 6, of universal access to malaria treatment. AMFm will test a new and complementary architecture of financing and development assistance for malaria drugs. Assessment of its first phase provides an opportunity to learn how well AMFm works and how it compares with traditional models of financing.

ContributorsBoth authors had the original idea for and wrote the paper.

Conflicts of interestOA is director of AMFm and was formerly coordinator of public-health programmes at the World Bank, where he led the project to develop AMFm. RA is director of the strategy, performance and evaluation cluster at The Global Fund.

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