

Piloting the Affordable Medicines Facility-malaria: what will success look like?

Gavin Yamey,^a Marco Schäferhoff^b & Dominic Montagu^c

Abstract The Affordable Medicines Facility-malaria is an innovative financing mechanism, managed by the Global Fund to Fight AIDS, Tuberculosis and Malaria. This initiative aims to increase the use of artemisinin-based combination therapies for treating malaria. A pilot is underway in eight countries to determine whether the mechanism reduces the consumer price of these drugs and increases their availability in public and private outlets, their market share and their use. To evaluate the pilot, an analysis was done to estimate predetermined “benchmarks” of success at 1 and 2 years. The analysis used a mixed-methods approach, triangulating data from a literature review with information from 33 interviews with experts. A sensitivity analysis and other methods were used to verify the results. Benchmarks used to determine success include an increase in availability of artemisinin-based combination therapies of 40 percentage points from baseline, and an increase in their use of 10–15 percentage points from baseline at year 2. These benchmarks were based on evidence that national public health programmes aimed at increasing the use of a specific health commodity in developing countries have generally achieved only modest changes in use within a 2-year time frame. Evaluation should also take individual country contexts into account.

Abstracts in **عربي**, **中文**, **Français**, **Русский** and **Español** at the end of each article.

Introduction

The Affordable Medicines Facility-malaria (AMFm) is an innovative financing mechanism that is managed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). The AMFm aims to increase use of artemisinin-based combination therapies (ACTs) by subsidizing prices. Although most malaria-endemic countries have adopted a policy of using ACTs as first-line treatment, household surveys in 18 African countries found that, in 2008, an average of only 3% of children aged less than 5 years with fever were treated with ACTs.¹ One reason for this low use rate is that 50–75% of patients in Africa and south-east Asia with suspected malaria seek care in the private sector, where ACT retail prices are high. For example, a course of ACT typically costs 6–10 United States dollars (US\$), about 10–20 times the cost of older monotherapies such as chloroquine or sulfadoxine-pyrimethamine.²

In the AMFm, a donor subsidy at the “factory gate” lowers the cost of ACTs purchased by eligible first-line buyers (i.e. those who buy them directly from the manufacturer).³ Proponents of the AMFm argue that the subsidy will in turn be passed along the supply chain to the consumer, lowering ACT prices so that they are comparable to chloroquine, sulfadoxine-pyrimethamine or artemisinin monotherapy. Reduced prices should, in theory, “crowd out” sales of these other drugs and thus increase ACT use.⁴ Reducing the use of artemisinin monotherapy is particularly important because such monotherapy may accelerate the development of artemisinin resistance.⁵ In addition to the price subsidy, the AMFm involves supportive interventions aimed at boosting ACT use, including in-country branding and associated awareness campaigns for sellers and patients, training for ACT providers and greater access to rapid diagnostic tests for malaria.

The success of the AMFm will be measured according to the following objectives:

- reduces the *price* of ACTs to a price comparable to that of other antimalarials;
- increases the *availability* of ACTs in public and private outlets;
- increases the *market share* of ACTs among antimalarials;
- increases the *use* of ACTs, including among poor rural communities.

A pilot study to test the AMFm – AMFm Phase 1, lasting about two years, – is underway in eight countries (Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, United Republic of Tanzania [including Zanzibar] and Uganda), and is managed by the national government in each of those countries. An independent evaluation is measuring progress against the four objectives. Data collection (end-line outline surveys) will be completed by December 2011 for all countries except mainland United Republic of Tanzania, where the final outlet surveys will be completed in January 2012.⁶ Based on this evaluation, the Global Fund Board will decide in 2012 whether to expand, accelerate, modify, suspend or terminate the AMFm. This decision will rest on a crucial question: What would constitute “success” in the AMFm Phase 1? In other words, at 1 or 2 years into the pilot, what changes in ACT price, availability, market share and use should be expected if the financing mechanism is working?

The AMFm Ad Hoc Committee, established to advise the Global Fund Board on the development, launch, implementation and evaluation of the AMFm pilot,⁷ recently commissioned us to estimate predetermined “benchmarks” of success at 1 and 2 years into the AMFm Phase 1. This paper summarizes the methods, findings and recommendations of that study; the full report is available on the Global Fund web site.⁸

^a Evidence to Policy Initiative, Global Health Group, University of California San Francisco, 50 Beale Street, San Francisco, CA, 94105, United States of America (USA).

^b SEEK Development, Berlin, Germany.

^c Health Systems Initiative, Global Health Group, University of California San Francisco, San Francisco, USA.

Correspondence to Gavin Yamey (e-mail: yameyg@globalhealth.ucsf.edu).

(Submitted: 27 May 2011 – Revised version received: 20 October 2011 – Accepted: 18 November 2011 – Published online: 3 February 2012)

Approach

We adopted a “mixed-methods” approach to estimating success benchmarks, triangulating data from a literature review and interviews with experts. Through the literature review, we collected available quantitative evidence on price, availability, market share and use from:

- four subnational pilot studies of ACT price subsidies;
- six national programmes to scale up subsidized ACTs;
- other national ACT scale-up initiatives;
- national campaigns to market subsidized commodities (contraceptives, water purification products, oral rehydration therapy, zinc and vitamin A).

We interviewed 33 experts worldwide to contextualize and cross-check the quantitative findings. Interviewees included researchers and implementers with expertise in malaria, social marketing experts, drug supply chain specialists, nongovernmental organizations (NGOs), and drug company executives from multinational and generic drug companies (see Appendix A for full list of interviewees).⁸ Advocates for the AMFm, sceptics and those who are neutral on the value of the initiative were all included in the interviews. We also received input from the AMFm Ad Hoc Committee, which includes representatives of ministries of health, international organizations and NGOs.

Based on the literature review and the interviews, we estimated benchmarks of success in the AMFm. To verify the results, we used two additional approaches – a weighted mean approach and a Monte Carlo multivariate sensitivity analysis (methods and results of these approaches are shown in Appendix F).⁸ The estimates derived from these approaches were similar to those derived from our initial triangulation approach, indicating that they were appropriate.

Pilot studies

Four small-scale trials, conducted in a few districts or municipalities, provide the most direct evidence for what success might look like in the AMFm Phase 1 (Table 1).^{9–12} Of these, only one (in Kenya)⁹ was randomized and one (in the United Republic of Tanzania)¹⁰ was quasirandomized.

These pilots provide “proof of principle” evidence that an ACT price subsidy can quickly increase ACT availability and market share, and lower consumer prices. In three pilots, the intervention districts saw a rapid rise from baseline in the proportion of private outlets stocking ACTs (from 0% at baseline to 69–81% at 1 year).^{10–12} Only one of these pilots included a control district, which saw a fall in this proportion (from 1% at baseline to 0% at 1 year).¹⁰ In the same three pilots, ACT market share increased rapidly in the intervention districts (from 0–1% at baseline to 38–51% at 1 year).^{10–12} In contrast, in the control district in the United Republic of Tanzania, there was only a small increase (from 0% at baseline to just 6% at 1 year).¹⁰ All four pilots found that ACT price subsidies were passed on to consumers, who paid prices that were similar to, or below, those of chloroquine or sulfadoxine-pyrimethamine.

The pilots found conflicting evidence on whether ACT subsidies are associated with changes in ACT use. The controlled, non-randomized trial in Uganda was negative (ACT use was higher in the control group) but a new intervention was introduced into the control district after the trial had started, making it hard to draw clear conclusions.¹¹ The cluster-randomized controlled trial in Kenya was positive: at 1 year, use increased from baseline by 40.2 percentage points in the intervention arm and by only 14.6 percentage points in the control arm.⁹

There is evidence from these pilots that ACT price subsidies may not reach poor, remote communities. For example, in the Uganda pilot, ACT market share was lower among poorer groups.¹¹ A secondary analysis of the United Republic of Tanzania pilot found that ACT availability in the intervention districts was lower in more remote outlets.¹³

Is it reasonable to set expectations for the AMFm based on these small pilots? Key informants urged us not to do so because, as outlined above, the pilots had several design flaws, and it is unlikely that results seen in small-scale pilots could easily be replicated at national scale.

National programmes

We found limited evidence on six national programmes that scaled up subsidized ACTs (Table 2). These re-

sults indicate the kind of impact a national ACT subsidy can have under “real world” conditions. We believe that two of these programmes – in Cameroon and Senegal – are a close model for the AMFm, because they are led by the national government, rather than by social marketing organizations.¹⁴ None of the national programmes compared intervention districts with control districts. Baseline data were available for only one programme (in Rwanda).¹⁵ These limitations made it difficult to assess the true impact of national ACT subsidies over time.

Data on ACT availability were found for three programmes. In Rwanda, availability of child ACTs increased rapidly, from 10% at baseline to 80–90% at 18 months.¹⁵ However, in Cambodia and Senegal, ACT availability in private outlets was still low at 1 year into the programme (22% in Cambodia and 44.8% in Senegal for adult ACTs).^{14,16} Data on market share were available from only one national programme: in Cambodia, ACTs accounted for 28% of all antimalarial sales in private outlets at 6 years into the programme. Examination of sales volumes of subsidized malaria treatment from Population Services International showed that, in many countries, sales volumes remained low in the first 2 years and that it took at least 3 years to reach substantial sale volumes.⁸

Quantitative data on consumer price were available for two programmes (Cambodia and Senegal). As shown in Table 2, private outlets bought ACTs at subsidized prices and sold them to consumers at a mark-up of 150% (Cambodia) and 35% (Senegal). In Cambodia, the ACT price was much higher than that of chloroquine (which cost US\$ 0.20); in contrast, in Senegal, the ACT price was lower than that of sulfadoxine-pyrimethamine (which cost US\$ 2). In Cameroon, the subsidy was only passed on to consumers in one of the three provinces surveyed (W Mbacham, University of Yaoundé, personal communication, 2010).

Data on ACT use were available from three programmes at a range of time points after the subsidy was launched: in the Democratic Republic of Congo, ACT use was 1% at about 1 year; in Madagascar, it was 2.4% at about 5 years; and in Senegal, it was 4% at about 2–3 years.^{17,18} Thus, the available data suggest that, with the

Table 1. Subnational pilots of subsidized artemisinin-based combination therapies

Country	Lead organization	Time frame	Design	Scale	Age group	Outlets	Change in ACT use at 1 year	ACT price at 1 year	ACT availability at 1 year	ACT market share at 1 year
Angola	Government, Mentor initiative	Ongoing	Uncontrolled	2 municipalities (95 pharmacies)	Children aged less than 5 years	Pharmacies	Usage data not reported	Pharmacies in intervention municipalities mostly kept to proposed price of US\$ 1 for child ACTs. Price was comparable to CQ and AQ.	69% Coartem B6 (smallest packet by weight); 81% Coartem B12 (next largest packet size) 0% at baseline	38% (0% at baseline)
Kenya	Government, PSI, LSHTM, KEMRI	1 year (ended May 2010)	Cluster randomized controlled trial	3 districts (all in 1 province), 18 clusters (6 in each district)	Children aged less than 5 years	Retail outlets	Intervention arm: 40.2% increase from baseline. Control arm: 14.6% increase	95% of caregivers in the intervention arm bought subsidized ACTs at RRP of US\$ 0.25	Not measured	Not measured
Uganda	Government, MMW	Ongoing (began in September 2008); results at 12 and 20 months are available	Non-randomized, controlled	4 intervention districts, 1 control district	All age groups	Drug shops, clinics	Intervention arm: use within 24 and 48 hours of fever onset: 15% and 20%, respectively (3% and 4%, respectively, at baseline); increase in usage was greater in control arm.	Intervention arm: 95% of people purchasing "ACT-leaf" (subsidized ACTs) paid the correct price	Intervention arm: 75% (child ACT); no baseline data available	Intervention arm: 51% (0% at baseline)
United Republic of Tanzania	Government, CHAI	1 year (ended November 2008)	Quasi-randomized trial	2 intervention districts, 1 control district	All age groups	Drug shops	Usage data not reported	Mean consumer price for ACTs: US\$ 0.58, close to mean RRP (US\$ 0.50); average price for adult ACTs not significantly different from price of SP (US\$ 0.67), but significantly higher than price of AQ (US\$ 0.48); mean price for child ACTs significantly less than SP (US\$ 0.51) and AQ (US\$ 0.86)	Intervention districts: 72.2% [mean of all age groups]; 0% at baseline. Control district: 1% (0% at baseline)	44.2% (1% at baseline) Control district: 6% (0% at baseline)

ACTs, artemisinin-based combination therapies; AQ, amodiaquine; CQ, chloroquine; CHAI, Clinton Health Access Initiative; KEMRI, Kenya Medical Research Institute; LSHTM, London School of Hygiene and Tropical Medicine; MMW, Medicines for Malaria Venture; PSI, Population Services International; RRP, recommended retail price; SP, sulfadoxine-pyrimethamine

Table 2. National programmes subsidizing artemisinin-based combination therapies^a

Country	Lead organization	Launch year	Age group	Outlets	Coverage	Outcome: ACT availability	Outcome: ACT price
Cambodia	PSI	2002	All age groups	Pharmacies, drug shops	17 of 20 malaria-endemic provinces	At 1 year: – very low in private facilities; 22% stocked adult ACTs; 6% stocked child ACTs	At 1 year: – mean consumer price for adult ACTs (US\$ 1.07) 70% higher than RRP (US\$ 0.63)
Cameroon	Government	2007	All age groups	Public and private health facilities	National	At 1 year: – low availability of subsidized ACTs at public or private facilities – monotherapies widely available	At 1 year: – adherence to RRP strong in only one province (Yaoundé Centre)
Democratic Republic of Congo	PSI	2006	Children aged less than 5 years	Pharmacies	Limited to some districts	At 2 years: – 20.2% (public facilities), 25.8% (part 1 pharmacies), 20% (drug shops), 8.6% (other private outlets) – 66.4% facilities stocked non-artemisinin-based therapy, 47.8% stocked AMT	At 2 years: – median price of ACTs: US\$ 2.75 (public health facilities), US\$ 2.29–4.58 (private facilities), US\$ 3.89 (all facilities selling ACTs) – ACT price 60% higher than price of the most common antimalarial in outlets selling ACTs
Madagascar	PSI	2003	Children aged less than 5 years	Pharmacies, private providers, community agents	National	At 5 years: – 85.6% (public facilities), 47.5% (part 1 pharmacies), 20% (drug shops), 0.1–16.5% (other private outlets) – 34.4% facilities stocked non-artemisinin-based therapy, 0.5% stocked AMT	At 5 years: – median price of ACTs in facilities selling ACTs: US\$ 4.04 (ACTs free in public facilities) – ACTs 11.3 times more expensive than the most common antimalarial in outlets selling ACTs
Rwanda	PSI	2007	Children aged less than 5 years	Pharmacies	National	At 18 months: – high ACT availability in private pharmacies: 80–90% stocked child ACTs (compared with 10% at baseline) – monotherapies effectively banned	Data unavailable
Senegal	Government	2006	All age groups	Pharmacies	National	At 1 year: – proportion of all facilities (public and private) stocking ACTs: 44.8% (adult dose), 58.2% (child), 46.3% (infant) – monotherapies widely available	At 1 year: – strong adherence to RRP in private outlets (observed mean retail price: US\$ 1.34; RRP: US\$ 1.31)

ACTs, artemisinin-based combination therapies; AMFm, Affordable Medicines Facility-malaria; AMT, artemisinin monotherapy; PSI, Population Services International; RRP, recommended retail price.

^a These programmes were rolled out before the 2010–11 AMFm pilot. Two countries, Cambodia and Madagascar, have also been included in the AMFm pilot phase, and the results from the pilot are due to be reported in 2012.

exception of Rwanda, national ACT subsidy programmes have generally not seen the rapid, large changes in ACT “success metrics” that were seen in the subnational pilots.

Other initiatives

We examined data on other initiatives that aimed to increase the availability and use of ACT – in particular, national public sector programmes supported by funding from the Global Fund. The success of these programmes can also help to guide expectations for the AMFm.

Generally, these initiatives have shown only modest success to date, particularly in increasing ACT use. For example, the 2009 external evaluation of the Global Fund concluded: “While there are data showing that most countries have purchased large amounts of ACT, there is little or no evidence of a corresponding increase in the use of ACT for treatment of children.”¹⁹ The evaluation found that in all surveyed countries (except for Zambia), fewer than 5% of children treated for fever received an ACT.

Social marketing

The AMFm involves supportive interventions to encourage increased and safe use of ACTs. These interventions include social marketing techniques, such as branding and communication campaigns targeted at both ACT sellers and consumers. To provide benchmarks on the potential impact of these supportive interventions, we examined the literature on the social marketing of other subsidized health commodities, to determine how a national-level social marketing campaign can change commodity coverage and use. We examined the literature on the social marketing of preventive tools (e.g. contraceptives, condoms, drinking water products) and treatment tools (e.g. zinc and oral rehydration therapy for treating acute diarrhoea).

The literature on socially marketed preventive tools suggests that it takes at least 3 years before a new product achieves high uptake. For example, two national studies on condoms and oral contraceptives found that market share at 3 years into the marketing programme was only 10–15%.^{20,21} Similarly, water purification products in east Africa were stocked in only 6–20% of shops 2 years

into the marketing campaign.^{22,23} These results are typical of social marketing campaigns.²⁴

With respect to treatment tools the literature also suggests that it is rare to see dramatic changes in uptake over short time periods. For example, a recent analysis of data from 40 countries on the social marketing of oral rehydration therapy to treat diarrhoea between 1986 and 2003 found an average annual increase in its use of only 0.39%.²⁵ The Scaling Up of Zinc for Young Children (SUZY) Project – a national programme to socially market subsidized zinc in Bangladesh – is a valuable model for the AMFm Phase 1, given the parallels between the two initiatives.²⁶ Both promote a product used for treating a life-threatening childhood illness, aim to crowd out other medications (anti-diarrhoeal drugs and antibiotics in the case of the SUZY Project) and involve a situation where most parents seek medical help in the private sector. In the SUZY Project, zinc usage increased by 8–15% from baseline at about 2 years. This outcome, heralded as a great public health success story, is helpful for setting expectations for the AMFm.²⁶

Emerging themes

Four recurring themes emerged from the interviews:

- The 2-year timescale of the AMFm Phase 1, with the initial impact evaluation at just 1 year into the programme, may be too short to see large changes in the four success metrics, particularly ACT use.
- ACT uptake is likely to be worse in remote, rural areas than in urban settings; thus, the AMFm may not “reach the last mile”.
- Rwanda’s successful national ACT subsidy programme is unlikely to be replicable in large countries with less-engaged governments and weak drug distribution systems.
- Many different factors are likely to determine the success of the different pilots, such as the quality of the supportive interventions, whether ACTs are available over the counter, and the urban–rural population ratio.

When interviewing drug company executives, we asked about their expectations when launching a new drug in a developing country market, to gain an additional “reality check” for what the

AMFm might be expected to achieve. The executives at multinational drug companies typically said that a market share of about 10% at 1 year and 20% at 2 years would be considered successful. Executives at generic drug companies in India generally had less ambitious metrics of success: about 5% at 1 year and 10% at 2 years.

Suggested benchmarks

Using the data summarized previously, we estimated benchmarks of success in a three-stage process. First, we used the range of results in the studies reviewed (information on a commodity’s price, availability, market share and use) as a starting point for the range of results that we believed were feasible in the AMFm at years 1 and 2. Second, we gave more weight to the results of studies of programmes closely resembling the AMFm (i.e. programmes that used a price subsidy and were rolled out nationally by governments). With the exception of Rwanda’s national ACT subsidy programme, these studies generally found little evidence that a subsidy has a rapid, large impact on the four ACT success metrics when tested at national scale. Finally, we took the interviewees’ views into account in deriving our estimates, shared our initial estimates with them, and then modified these estimates based on their input.

The suggested benchmarks are shown in Table 3. They are intended as a tool for tailoring expectations of what can be achieved in the 2-year time frame of the AMFm Phase 1. The benchmarks are not minimum cut-off points for “pass” or “fail”, and they will need to be interpreted in the light of relevant contextual factors.

A crucial contextual factor is the date when the subsidized ACTs arrive in the pilot country. This date varied between the eight pilot countries, and those countries that received subsidized ACTs soon after the launch of the pilot are more likely to have reached the benchmarks shown in Table 3. The suggested benchmarks are intended to be applied on a “country by country” basis (rather than as a “one size fits all” approach), and are thus based on relative percentage point changes from baseline (rather than on absolute thresholds). These benchmarks have been presented to the AMFm Ad Hoc Committee and the Global Fund Board. The committee

Table 3. **Estimated benchmarks of success of programmes subsidizing artemisinin-based combination therapies at 1 and 2 years**

	Year 1	Year 2
Price: ^a adult equivalent treatment dose	QAACT price < 300% of the price of the dominant non-QAACT (in most countries this is CQ or SP) AND price of AMFm co-paid QAACT < price of AMT (this is useful but not sufficient to determine success)	QAACT price < 150% of the price of the dominant non-QAACT (in most countries this is CQ or SP) AND price of AMFm co-paid QAACT < price of AMT (this is useful but not sufficient to determine success)
Availability: proportion of all facilities, private and public (including informal outlets), stocking QAACTs among outlets with any antimalarials in stock at the time of the survey	Increase of 20 percentage points from baseline	Increase of 40 percentage points from baseline
Market share: total volume of QAACTs sold or distributed as a proportion of the total volume of all antimalarials sold or distributed in the previous 7 days via outlets that will be included in the independent evaluation's surveys	Increase in ACT market share of 10–15 percentage points from baseline AND decrease in market share of AMT from baseline	Increase in ACT market share of 15–20 percentage points from baseline AND decrease in market share of AMT from baseline
Use: ^b proportion of children aged less than 5 years with fever who received a QAACT on the day that the fever started or on the following day	Increase of 5–10 percentage points from baseline	Increase of 10–15 percentage points from baseline

ACT, artemisinin-based combination therapy; AMFm, Affordable Medicines Facility-malaria; AMT, artemisinin monotherapy; CQ, chloroquine; QAACT, quality-assured ACT (an ACT that has met the Global Fund's quality assurance policy); SP, sulfadoxine-pyrimethamine

^a Price change was the indicator with the weakest empirical basis for setting a 1-year expectation.

^b The denominator for ACT use is "fever episodes in children aged less than 5 years" (not "parasitologically confirmed malaria cases"). The independent evaluation relies on national surveys (e.g. Demographic and Health Surveys; Multiple Indicator Cluster Surveys; Malaria Indicator Surveys; ACTwatch surveys) that use this denominator due to a lack of proper malaria diagnosis in many countries.

and board will determine whether or not they will be used as the basis for future decisions about the continuation or termination of the AMFm.

The methodology used to develop the benchmarks has limitations. For example, the approach drew on inferences across countries, supply and subsidy methods, and programme targets, and involved both literature review and interviews. This form of triangulation does not permit traditional sensitivity analysis.²⁷

Conclusion

Given the weaknesses in the evidence on whether ACT subsidies work, the outcome of the AMFm Phase 1 cannot be predicted with certainty. Previous pilots of ACT subsidies were small scale, and only one was fully randomized; data from national subsidy programmes are limited. We used the available evidence from these pilots and programmes, plus evidence on scaling up health commodities and the experiences of experts in the field, to derive benchmarks for what success would look like in an AMFm Phase 1 country, as shown in Table 3.

The totality of the evidence suggested that expectations should not be set too high for the AMFm Phase 1. National public health programmes aimed

at increasing the use of a specific health commodity in low-income countries have generally achieved only modest changes in use within a 2-year time frame. We believe that our suggested benchmarks are derived from the most appropriate evidence available, and are both pragmatic and achievable.

Our analysis was specifically aimed at estimating predetermined benchmarks of success in the AMFm pilot, not at determining in detail the potential factors that could influence whether pilot countries succeed or fail to reach these benchmarks. These potential factors, some of which were discussed in a recent commentary by Sabot and colleagues,²⁸ are likely to include managerial and implementation capacity at national and "supranational" level (i.e. within the Global Fund), the quality of the supportive interventions that each pilot country rolls out, and the strength of each country's drug supply chain. Sabot and colleagues also argue that the cost-effectiveness of the AMFm is likely to depend on the level of malaria endemicity in the pilot country, and that the AMFm will have low cost-effectiveness in countries with a low burden of disease.²⁸

We believe that this is the first benchmarking assessment commissioned for a global public health inter-

vention in which the benchmarks of success have been determined ahead of an independent evaluation of a pilot. For example, initiatives such as the United States President's Malaria Initiative or the GAVI Alliance do not appear to have predetermined measures of success or failure. The unique nature of the AMFm benchmarking exercise made it challenging but perhaps also groundbreaking in the field of global public health programming. ■

Funding: This study was funded by a grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria to the University of California, San Francisco (UCSF Award A115807). It included travel costs for Gavin Yamey and Marco Schäferhoff to attend two meetings of the AMFm Ad Hoc Committee and for Gavin Yamey to attend a Global Fund Board meeting.

Competing interests: Gavin Yamey declares that the Evidence to Policy Initiative at UCSF has also received funding from the Clinton Health Access Initiative, which conducted several studies cited in this paper (references 10, 13 and 16), and from the Bill & Melinda Gates Foundation, a funder of the AMFm pilot phase. Dominic Montagu declares that the Health Systems Initiative at UCSF has received funding from ExxonMobil to engage

private pharmaceutical wholesalers in dialogues with national malaria control programmes and AMFm policy-makers,

and from the Bill & Melinda Gates Foundation. Marco Schäferhoff is currently managing a project commissioned by the

Global Fund and conducted by SEEK Development on technical assistance contributions of major Global Fund donors.

ملخص

التنفيذ التجريبي لمرقق الأدوية ميسورة التكلفة - الملاريا: ما الشكل الذي سيكون عليه النجاح؟

حساسية وأساليب أخرى للتحقق من النتائج. وتتضمن القياسات المرجعية المستخدمة لتحديد النجاح زيادة في إتاحة العلاج التوليفي بالأرتيميسينين بمقدار 40 نقطة مئوية من خط الأساس، وزيادة في استخدامه بما يتراوح ما بين 10 إلى 15 نقطة مئوية من خط الأساس في السنة الثانية. واعتمدت القياسات المرجعية هذه على البيانات التي تفيد بأن برامج الصحة العمومية الوطنية الرامية إلى زيادة استخدام سلعة صحية محددة في البلدان النامية لم تحقق عمومًا سوى تغييرات متواضعة من حيث الاستخدام خلال إطار زمني مدته عامين. ويتعين أيضًا أن يأخذ التقييم سياقات البلدان الفردية في الحسبان.

مرقق الأدوية ميسورة التكلفة - الملاريا هو آلية تمويل مبتكرة يديرها الصندوق العالمي لمكافحة الإيدز والسل والملاريا. وتهدف هذه المبادرة إلى زيادة استخدام العلاج التوليفي بالأرتيميسينين في علاج الملاريا. ويتم إجراء تنفيذ تجريبي في ثمانية بلدان لتحديد ما إذا كانت الآلية تخفض أسعار المستهلك الخاصة بهذه الأدوية وتزيد من إتاحتها في المنافذ العمومية والخاصة ونصيبيها من السوق واستخدامها. ولتقييم التجربة، تم إجراء تحليل لتقييم "القياسات المرجعية" المحددة سابقًا للنجاح في العامين الأول والثاني. واستخدم التحليل نهج الأساليب المختلطة، مع التقسيم المثلثي للبيانات من الأبحاث المنشورة التي تحتوي على معلومات مستقاة من 33 مقابلة تم إجراؤها مع خبراء. وتم استخدام تحليل

摘要

试行疟疾平价药品机制：成功的模样如何？

疟疾平价药品机制是由全球艾滋病、结核病和疟疾防治基金管理的一种创新融资机制。这一举措旨在增加治疗疟疾的基于青蒿素的联合疗法的使用。试点正在八个国家展开，用以确定此机制是否能够降低这些药物的消费价格，提高其在公共和私营网点的可用性、其市场份额及其使用。为评估试点效果，进行了一项分析来估量第1年和第2年预定的成功“基准”。分析使用混合方法途径，从包含

来自33个专家访谈资料的文献回顾中进行数据三角测定。使用敏感性分析和其他方法验证结果。用来确定成功的基准包括基于青蒿素的联合疗法的可用性从基线增加40个百分点，在第2年其使用增加10-15个百分点。这些基准所基于的证据是旨在增加发展中国家特定卫生商品使用的国家公共卫生计划在2年的时间框架内实现的变化并不十分显著。评估也应考虑到单独国家的具体情况。

Résumé

Pilotage du Fonds pour des médicaments antipaludéens à des prix abordables: quel type de succès?

Le Fonds pour des médicaments antipaludéens à des prix abordables est un mécanisme de financement innovant, géré par le Fonds mondial de lutte contre le Sida, la tuberculose et la malaria. Cette initiative vise à accroître l'utilisation des associations thérapeutiques à base d'artémisinine dans le traitement du paludisme. Un projet pilote est en cours dans huit pays afin de déterminer si ce mécanisme réduit le prix de ces médicaments pour le consommateur et augmente leur disponibilité dans les magasins publics et privés, leur part de marché et leur utilisation. Pour évaluer le projet pilote, une analyse a été réalisée afin d'établir des critères prédéterminés de succès à 1 et 2 ans. L'analyse a eu recours à une approche de méthodes mixtes, corrélant des données issues de la littérature avec les informations recueillies lors de 33 entretiens avec

des experts. Une analyse de sensibilité et d'autres méthodes ont été utilisées pour vérifier les résultats. Les critères utilisés pour déterminer le succès incluent une augmentation de la disponibilité des traitements à base d'artémisinine de 40 pour cent par rapport au départ et une augmentation de leur utilisation de 10 à 15 pour cent par rapport au départ pour l'année 2. Ces critères sont basés sur le constat que les programmes nationaux de santé publique visant à accroître l'utilisation d'un produit de santé spécifique dans les pays en développement n'ont généralement conduit qu'à de modestes changements des habitudes sur une période de 2 ans. L'évaluation devrait également tenir compte des contextes nationaux spécifiques.

Резюме

Открытие Глобального фонда борьбы со СПИДом, туберкулезом и малярией «Affordable Medicines Facility-malaria»: успех – каким он будет?

Глобальный фонд борьбы со СПИДом, туберкулезом и малярией начинает использовать новый механизм в области финансирования здравоохранения – «Affordable Medicines Facility-malaria». Цель данной инициативы заключается во внедрении комбинированных типов терапии малярии на основе артемизинина. Это пилотная программа в данный период внедряется в 8 странах для определения того, может ли

данный механизм снизить потребительскую цену используемых препаратов и повысить их доступность в общественных и частных каналах сбыта. Для оценки этой пилотной программы был проведен анализ для предварительного определения степени успешности через 1 и 2 года. Для проведения анализа был применен подход со смешанными методами, с использованием триангулированных данных, взятых из обзора литературы,

conteniendo información de 33 entrevistas con médicos especialistas. El análisis de sensibilidad y otros métodos también fueron aplicados para verificar los resultados. Los criterios utilizados para determinar el éxito incluyen el aumento de la disponibilidad de los medicamentos combinados con artemisinina para el tratamiento de la malaria. Se está llevando a cabo un estudio preliminar en ocho países para determinar si este mecanismo reduce el precio de dichos fármacos para el consumidor y si incrementa su disponibilidad en distribuidores públicos y privados, su cuota de mercado y su uso. Con el fin de evaluar el estudio preliminar, se llevó a cabo un análisis para estimar unas «referencias» de éxito predeterminadas en uno y dos años. El análisis empleó un enfoque que combinaba diversos métodos, comparando datos de una revisión bibliográfica con la información

obtenida a partir de 33 entrevistas con expertos. Se emplearon tanto un análisis de sensibilidad como otros métodos para verificar los resultados. Las referencias utilizadas para determinar el éxito incluyen un aumento de 40 puntos porcentuales en la disponibilidad de las terapias combinadas con artemisinina desde la fecha inicial y un incremento en su uso de entre 10 y 15 puntos porcentuales desde la fecha inicial hasta el segundo año. Estas referencias se basaron en la evidencia de que, generalmente, los programas sanitarios públicos nacionales que pretendían incrementar el uso de un producto sanitario en países en desarrollo, solo habían generado cambios moderados en el uso de los mismos durante un plazo de dos años. La evaluación también debería tener en cuenta contextos individuales por país.

Resumen

Estudio preliminar sobre el Mecanismo de Medicinas Asequibles para la Malaria: ¿cómo se medirá el éxito?

El Mecanismo de Medicinas Asequibles para la Malaria es un innovador sistema de financiación gestionado por el Fondo Mundial de lucha contra el SIDA, la tuberculosis y la malaria. Esta iniciativa pretende incrementar el uso de las terapias combinadas con artemisinina para el tratamiento de la malaria. Se está llevando a cabo un estudio preliminar en ocho países para determinar si este mecanismo reduce el precio de dichos fármacos para el consumidor y si incrementa su disponibilidad en distribuidores públicos y privados, su cuota de mercado y su uso. Con el fin de evaluar el estudio preliminar, se llevó a cabo un análisis para estimar unas «referencias» de éxito predeterminadas en uno y dos años. El análisis empleó un enfoque que combinaba diversos métodos, comparando datos de una revisión bibliográfica con la información

obtenida a partir de 33 entrevistas con expertos. Se emplearon tanto un análisis de sensibilidad como otros métodos para verificar los resultados. Las referencias utilizadas para determinar el éxito incluyen un aumento de 40 puntos porcentuales en la disponibilidad de las terapias combinadas con artemisinina desde la fecha inicial y un incremento en su uso de entre 10 y 15 puntos porcentuales desde la fecha inicial hasta el segundo año. Estas referencias se basaron en la evidencia de que, generalmente, los programas sanitarios públicos nacionales que pretendían incrementar el uso de un producto sanitario en países en desarrollo, solo habían generado cambios moderados en el uso de los mismos durante un plazo de dos años. La evaluación también debería tener en cuenta contextos individuales por país.

References

1. *World malaria report*. Geneva: World Health Organization;2008. Available from: <http://www.who.int/malaria/wmr2008> [accessed 19 January 2012]
2. Moon S, Pérez Casas C, Kindermans J-M, de Smet M, von Schoen-Angerer T. Focusing on quality patient care in the new global subsidy for malaria medicines. *PLoS Med* 2009;6:e1000106. doi:10.1371/journal.pmed.1000106 PMID:19621068
3. *First-line buyers of ACT: eligibility criteria*. Geneva: The Global Fund to Fight AIDS, Tuberculosis and Malaria; 2012. Available from: <http://www.theglobalfund.org/en/amfm/firstlinebuyers/eligibility/> [accessed 27 January 2012].
4. *Affordable Medicines Facility - malaria: technical design*. Geneva: Roll Back Malaria Partnership; 2007. Available from: <http://www.rbm.who.int/partnership/tf/globalsubsidy/AMFmTechProposal.pdf> [accessed 19 January 2012].
5. *Understanding the antimalarial market: Uganda 2007*. Geneva: Medicines for Malaria Venture; 2007.
6. *Independent evaluation of the Affordable Medicines Facility - malaria (Phase 1): inception report*. Fairfax, VA: ICF Macro; 2010.
7. *Report of Affordable Medicines Facility - malaria, Ad Hoc Committee*. Geneva: The Global Fund to Fight AIDS, Tuberculosis and Malaria; 2009. Available from: http://www.theglobalfund.org/documents/board/19/BM19_07AMFmCommittee_Report_en/ [accessed 27 January 2012].
8. Schäferhoff M, Yamey G. *Estimating benchmarks of success in the Affordable Medicines Facility - malaria Phase 1*. San Francisco: Evidence-to-Policy Initiative; 2011. Available from: http://www.theglobalfund.org/documents/amfm/E2PI_EstimatingBenchmarksInAMFm_Report_en/ [accessed 19 January 2012].
9. Kangwana B, Kedenge SV, Noor AM, Alegana VA, Nyandigisi AJ, Pandit J, et al. *The impact of retail sector delivery of artemether-lumefantrine on effective malaria treatment of children under five in Kenya*. Nairobi: Kenya Medical Research Institute; 2009. Available from: <http://www.tropika.net/specials/mim2009/session-reports/scientific-session-9-docs/76-Beth-Kangwana-1535-1550hrs.pdf> [accessed 19 January 2012].
10. Sabot OJ, Mwita A, Cohen JM, Ipuge Y, Gordon M, Bishop D et al. Piloting the global subsidy: the impact of subsidized artemisinin-based combination therapies distributed through private drug shops in rural Tanzania. *PLoS ONE* 2009;4:e6857. doi:10.1371/journal.pone.0006857 PMID:19724644
11. *The impact of subsidized ACTs in Uganda's private sector*. Geneva: Medicines for Malaria Venture;2010.
12. *Pilot study: private sector distribution of artemisinin-based combination therapy (ACT) in Angola*. Preliminary 3rd quarter report, April 2010 to June 2010. Crawley: MENTOR Initiative;2010.
13. Cohen JM, Sabot O, Sabot K, Gordon M, Gross I, Bishop D et al. 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* 2010;10(Suppl 1):S6. doi:10.1186/1472-6963-10-S1-S6 PMID:20594372
14. Kone KG, Ndonky A, Lalou R, Le Hesran J-Y. *Subsidized ACTs available for sale in private drugstores: experience in Senegal*. Paris: Institute de Recherche pour le Developpement; 2007.
15. *Rwanda application form - Affordable Medicines Facility - malaria*. Geneva: The Global Fund to Fight AIDS, Tuberculosis and Malaria; 2010. Available from: www.theglobalfund.org/grantdocuments/RWN-R05-ML-AMFmApplication_0_en [accessed 31 January 2012].
16. Sabot OJ, Yeung S, Pagnoni F, Gordon M, Petty N, Schmits K, et al. *Distribution of artemisinin-based combination therapies through private sector channels: lessons from four country case studies*. Washington: Resources for the Future; 2009. Available from: http://www.rff.org/RFF/Documents/RFF-DP-08-43_FINAL.pdf [accessed 19 January 2012].
17. *Childinfo malaria treatment*. New York: United Nations Children's Fund; 2012. Available from: http://www.childinfo.org/malaria_tables1.php [accessed 19 January 2012].
18. ACTwatch [internet site]. Available from: <http://www.actwatch.info/home/home.asp> [accessed 19 January 2012].
19. *Five-year evaluation. Study area 3: Impact on HIV, TB, and malaria*. Geneva: The Global Fund to Fight AIDS, Tuberculosis and Malaria; 2010. Available from: <http://www.theglobalfund.org/en/terg/evaluations/5year/> [accessed 19 January 2012].
20. Purdy CH. Fruity, fun and safe: creating a youth condom brand in Indonesia. *Reprod Health Matters* 2006;14:127-34. doi:10.1016/S0968-8080(06)28256-9 PMID:17101431
21. Janowitz B, Suazo M, Fried DB, Bratt JH, Bailey PE. Impact of social marketing on contraceptive prevalence and cost in Honduras. *Stud Fam Plann* 1992;23:110-7. doi:10.2307/1966540 PMID:1604457
22. *Tanzania (2006): MAP study evaluating coverage and quality of coverage of Salam, Ngao and WaterGuard*. Washington: Population Services International; 2006. Available from: http://www.psi.org/sites/default/files/publication_files/672-tanzania_map_h2o_smrs.pdf [accessed 19 January 2012].
23. *Bénin (2009): mesure de la couverture et de la qualité de couverture du kit de traitement de diarrhée Orasel-Zinc® et du produit de traitement à domicile de l'eau Aquatabs® dans les départements du Bénin*. Washington: Population Services International; 2010. Available from: http://www.psi.org/sites/default/files/publication_files/2009-benin_map_h2o_ors_msr.pdf [accessed 19 January 2012].

24. Agha S, Do M, Armand F. *When donor support ends: the fate of social marketing products and the markets they help create*. Bethesda MD: Abt Associates; 2005. Available from: http://pdf.usaid.gov/pdf_docs/PNADF982.pdf [accessed 19 January 2012].
25. Forsberg BC, Petzold MG, Tomson G, Allebeck P. Diarrhoea case management in low- and middle-income countries—an unfinished agenda. *Bull World Health Organ* 2007;85:42–8. doi:10.2471/BLT.06.030866 PMID:17242757
26. Larson CP, Saha UR, Nazrul H. Impact monitoring of the national scale up of zinc treatment for childhood diarrhea in Bangladesh: repeat ecologic surveys. *PLoS Med* 2009;6:e1000175. doi:10.1371/journal.pmed.1000175 PMID:19888335
27. Rutherford GW, McFarland W, Spindler H, White K, Patel SV, Aberle-Grasse J et al. Public health triangulation: approach and application to synthesizing data to understand national and local HIV epidemics. *BMC Public Health* 2010;10:447. doi:10.1186/1471-2458-10-447 PMID:20670448
28. Sabot O, Gordon M, Moonen B, Talisuna A, Amofah G. A path to the optimal future for the Affordable Medicines facility-malaria. *Health Policy Plan* 2011;26:441–4. doi:10.1093/heapol/czr067