

Expert Consultation on the Procurement & Financing of Antimalarial Drugs

**15-16 September 2003
World Bank, Washington DC**

Meeting Report

DRAFT 3– 07 NOVEMBER 2003



BACKGROUND

With the failure of the malaria eradication efforts in the 1960's and 70's, developing countries have witnessed a resurgence of malaria, including re-introduction of malaria into areas where transmission had been interrupted. Currently, it is estimated that 300 to 500 million cases of malaria occur each year, resulting in more than 1 million deaths.

One of the engines driving this resurgence has been the development of resistance to traditional first-line antimalarial treatments. The situation has been most severe in parts of Southeast Asia and Latin America, where drugs like chloroquine (CQ) and sulfadoxine-pyrimethamine (SP or Fansidar[®]) have long since lost their effectiveness. In some areas, resistance to even newer drugs, such as mefloquine, has developed.

In sub-Saharan Africa, many countries continue to use CQ and SP as first-line treatment, but are witnessing growing numbers of treatment failures to these drug therapies. In the face of intensifying resistance to these first-line treatments, countries are beginning to revise their antimalarial drug policies and explore alternative treatment options.

Experience in some areas of Southeast Asia has demonstrated that combination therapy containing artemisinin-based drugs, so-called artemisinin-based combination therapy or ACT, has been successful in reversing the spread of drug-resistant malaria and reducing malaria burden. Based on such evidence, WHO has modified its guidance to countries to promote the use of ACT in countries where a new drug policy is required.

Artemisinin-containing combination therapies (ACT) come at a significantly increased cost (as much as a 20-fold increase per course of treatment). Affected countries and various partners in the Roll Back Malaria (RBM) Partnership are justifiably concerned about how countries and persons with malaria will be able to bear the incremental costs of these newer drugs. This issue has become particularly pressing in a small number of countries in sub-Saharan Africa. Worsening resistance to CQ and SP has precipitated these countries to change their drug policies and adopt ACTs as first-line drug treatment. These countries have encountered financial and non-financial barriers to implementing these changes.

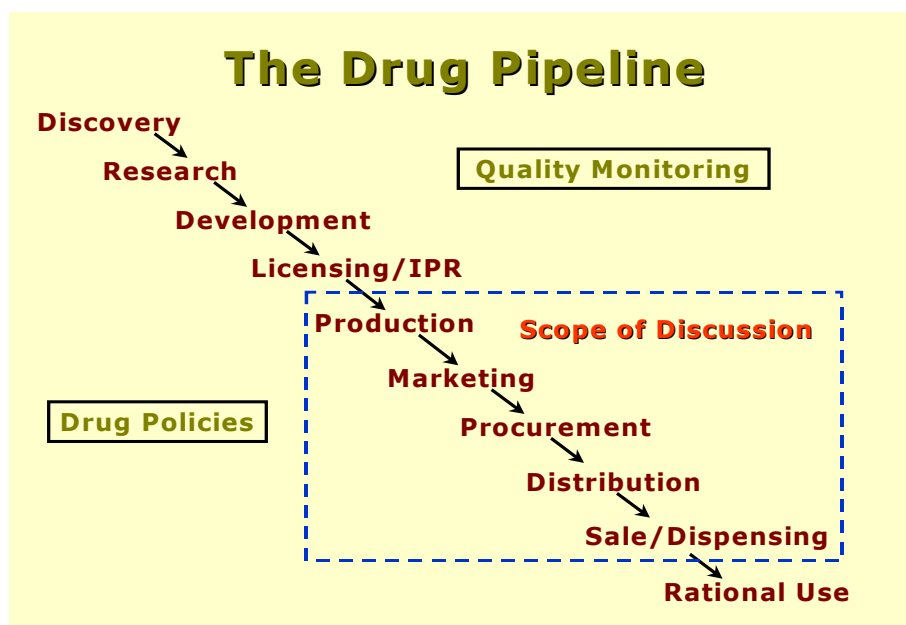
The majority of the burden of moving to more costly drugs will be borne by consumers, because 60% to 80% of all malaria treatments are purchased in the formal and informal private sector. Even with current drugs, many people cannot afford to purchase a full course of treatment. Use of sub-therapeutic doses is known to be one of the factors that drives the development of drug resistance. Promoting treatments that are significantly more costly is likely to exacerbate this problem. Aggressive solutions in the private sector will be needed.

Against this background, an “*Expert Consultation the Procurement and Financing of Antimalarial Treatment*” was hosted by the World Bank, on behalf of the RBM Partnership, on September 15-16, 2003. Experts in the areas of pharmaceutical policy, malaria control, health economics, health financing, drug procurement were brought together with representatives of malaria-affected countries and key RBM partner agencies to review a range of possible options for investment that would optimize access to and affordability of highly-effective antimalarial treatment in malaria-affected countries.

The goal of this expert consultation was to assist the RBM Partnership to target its support and resources most effectively to optimize the affordability of highly effective antimalarial treatment to persons in malaria-affected countries. There were three objectives for the meeting:

1. To assess various procurement models at global and country levels for reducing the cost to purchasers of highly effective antimalarial drug therapies in both the public and private sectors.
2. To develop recommendations to the RBM Board on preferred mechanisms for reducing cost of malaria treatment at the global level.
3. To provide guidance to countries on financing and procurement options at country level to reduce the cost of malaria treatment for consumers in both the public and private sectors.

This meeting was jointly commissioned by the RBM Working Group on Case Management, the Working Group on Finance and Resource Mobilization, and the Institute of Medicine (IOM) Committee on the Economics of Antimalarial Drugs. The findings and recommendations of this meeting will be submitted to the two working groups for review prior to submission to the RBM Partnership Board for action. The findings will also be submitted for consideration to the IOM Committee.



This consultation focused specifically on potential mechanisms that could reduce the cost of drugs at the levels of production, procurement, distribution, and sale/dispensing. Issues related to drug discovery and development, intellectual property, and rational drug use have been addressed in other forums, including as the Medicines for Malaria Venture, the World Trade Organization, and the RBM Working Group on Case Management.

SUPPLY AND DEMAND FOR ANTIMALARIAL DRUGS

Artemisinin Availability, Formulations, and Current Prices

In the short to medium-term, ACTs represent the best option for first-line treatment in countries where CQ and SP are failing. A few other drugs and drug combinations are currently in development and may be useful alternatives or adjuncts to ACTs in the medium to long-term. This discussion will, therefore, focus on the availability of ACTs, and the artemisinin-based components of these combinations.

Artemisinin Availability

At present, there are six known producers of raw artemisinin (3 in Viet Nam, 2 in India, 1 in China) and 13 producers of the finished drug product (4 in Europe, 7 in Asia, 1 in Africa) (J.M. Kindermans, unpublished data). Production is concentrated in Asia, in large part, because current use of artemisinin-based compounds is limited mostly to this region. Countries in Africa, except South Africa, have yet to scale up use of ACTs. Global demand for artemisinin-based compounds and ACTs, therefore, is low.

The limited availability of raw artemisinin and the lack of real competition among producers of the raw material appear to be major barriers to scaling-up production and are partially responsible for its high price.

Enough raw material is currently produced worldwide to generate 20-30 million treatments of artemisinin-based therapy per year. It is estimated that 12-18 months advance notice is needed to significantly increase production of the raw material. Bearing in mind the estimated 300-500 million cases of malaria globally, there will be a need for significant scale-up of artemisinin production, particularly as distribution capacity is improved.

Given existing production capacity, it would most likely be easier in the short term to scale-up production of the raw material in Asia than to establish capacity in Africa. The long-term benefits of establishing production capacity in Africa must also be considered.

The availability of a synthetic artemisinin probably would result in a decrease in the cost of the raw material, translating into a lower cost for the finished product. The likelihood that such a synthetic will be available in the short to medium-term is small.

Formulations & Current Prices

Coartem[®]

Coartem[®] (Novartis), a combination of artemether and lumefantrine, is currently the only WHO-registered ACT. An agreement with WHO makes Coartem[®] available for public sector procurement at US\$2.4 for an adult dose and US\$0.9 for a child's dose (sold by

Novartis below current cost at an approximate US\$0.3 loss per adult treatment). The patent for Coartem[®] is no longer held by Novartis, but by its partner company in China.

Currently and projected availability of artemisinin-based compounds and combinations

Formulation	Manufacturer	Availability Estimates
Artesunate	Guilin	7 million treatments/year, 3 million available for Africa
Artesunate	Sanofi	Several million treatments/year
AS+AQ (blister)	Sanofi	Currently 500,000/year, but could increase to several million within months
AS+AQ (blister)	Cipla	Could produce 500,000 treatments within a few weeks
Coartem [®]	Novartis	2 million treatments/year (in 2001)

(Courtesy of J.M. Kindermans)

Non-WHO Registered Formulations

Over the past 5 years, a number of smaller manufacturers, particularly in Asia, have formulated artemisinin-based drugs and combinations that have not yet been registered in Europe, the United States, or by WHO. One significant hurdle to their registration is that their production facilities do not operate under “Good Manufacturing Practice” (GMP). There is also a lack of agreed international standards for ACTs. Limited efforts are currently underway to upgrade some production facilities to GMP standards. Manufacturers and prices are listed below:

Manufacturer and Current Prices for Artesunate (600mg) and Artesunate plus Amodiaquine Blister Presentations

Manufacturer	Product	Price (2003 US\$)
Guilin (China)	Artesunate	1.20
Sanofi (France)	Artesunate	1.76
Sanofi (France)	AS+AQ	adult :1.76 adolescent:1.35 child: 1.00
Cipla (India)	Artesunate	1.35
Cipla (India)	AS+AQ	adult: 1.50 adolescent: 0.75 child: 0.40
Dapfra (Belgium)	AS+AQ	adult: 1.29 - 2.46
Mepha (Switzerland)	Artesunate	2.46
Hanoi College of Pharm (future, Viet Nam)	Artesunate	0.50
Hanoi College of Pharm (future, Viet Nam)	AS+AQ	<0.80
Medicamen (India)	AS+AQ	<1.5

(Adapted from J.M. Kindermans)

An Estimation of Drug Requirements and Cost Implications in sub-Saharan Africa

Estimates of projected requirements for ACTs and their costs were developed through modeling of existing information for both the global level and at country level, using Zambia as an illustrative case (Y Derriennic and B Mensah. September 2003. Financing of Artemisinin-Based Combination Antimalarial Drug Treatment. Technical Report No. 023. Bethesda, MD: The Partners for Health Reform *plus* Project, Abt Associates Inc.).

Modeling Parameters

The model utilized to calculate low, medium, and high estimates was based on the following measurements and projections:

- Estimated number of episodes per year- 400 million cases
- Percentage of cases treated with modern antimalarials- 60%
- Price of ACTs
 - o Cost of treatment calculated using a breakdown of episodes by age group multiplied by the cost of treatment for that age/weight¹
 - o Cost of CQ and SP is subtracted to yield the incremental cost of ACTs
 - o Scenarios
 - Lower Price Estimate: Price of AQ+AS drops quickly as demand increases falling below the price floor of plant-based production (est. \$0.55-\$0.70) and approaching \$0.35-\$0.40 per adult treatment.
 - Medium Price Estimate: Prices drop rather quickly in three years but then remain stable at approximately \$0.55-\$0.60 per adult treatment.
 - Higher Price: Prices decline slowly, reaching \$0.55-\$0.60 per adult treatment in eight years and then stabilizing
 - Coartem[®]: Price remains stable at \$2.40 per adult treatment until year 10 when it falls to by 33% (high), 45% (medium), or 55% (low).
- Speed of ACT adoption and coverage
 - o Major determinant of uptake will be drug price
 - o Prescription patterns will remain constant, continuing to provide treatment based on symptoms alone (i.e., treating many false positives).

Estimates of the Incremental Cost of Introducing ACTs in sub-Saharan Africa and Zambia

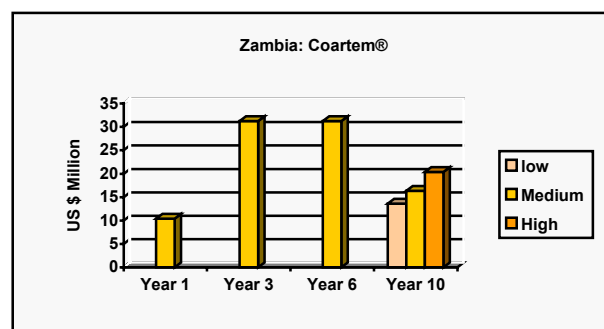
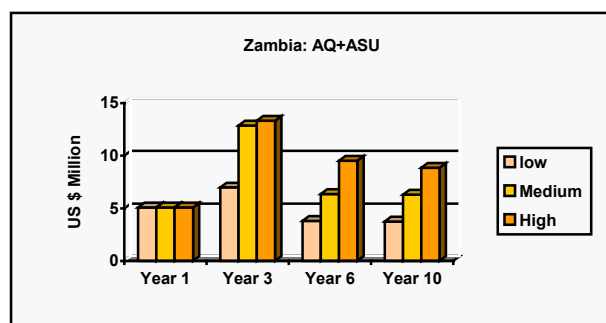
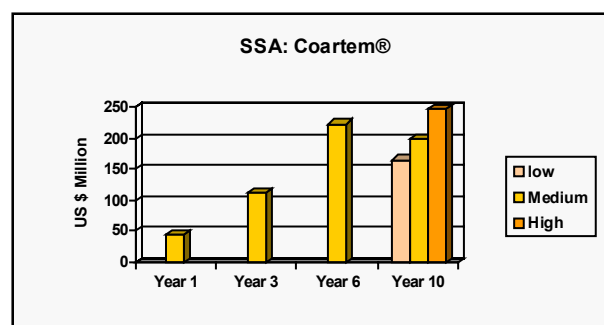
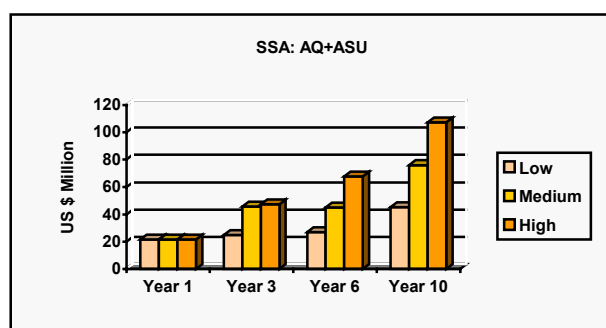
Using these models for sub-Saharan Africa, the incremental increase in cost per year for the combination of AS+AQ begins at \$22 million for Year 1 for all three scenarios. At Year 3, the incremental cost rises to \$25 million, \$46 million, and \$47 million, respectively for the low, medium, and high cost estimates. By Year 6, incremental costs

¹ Based on Snow et al (2003) Estimating the needs for artesunate-based combination therapy for malaria case-management in Africa, *Trends in Parasitology*, 19(8): 363-9.

remain relatively stable for the low (\$27 million) and the medium (\$45 million) estimates, but increases to \$68 million for the high estimate. For Coartem[®], incremental costs for all three estimate levels is \$45 million in Year 1, \$111 million in Year 3, and \$223 in Year 6.

For the case of Zambia, incremental costs begin in Year 1 at \$5 million for AS+AQ and \$10 million for Coartem[®] in all three scenarios. Low, medium, and high price estimates for AS+AQ in Year 3 are \$7 million, \$13 million, and \$13 million, respectively. By Year 6, the incremental cost of AS+AQ has dropped to \$4 million, \$6 million, and \$10 million for the low, medium, and high prices. Coartem[®] costs for Year 3 and Year 6 are both \$31 million.

Incremental Drug Costs of Introduction of ACTs in sub-Saharan Africa and Zambia



Impact of the Introduction of ACTs on Current Expenditures: Zambia

Yearly Impact	AQ+ASU	Coartem [®]
% Total Public Sector Expenditures	5.78%	12%
% Total Drug Budget (needs-based)	28%	58%
% Actual Drug Expenditures (2002)	45%	93%

Conclusions

1. Current and projected levels of production will fall far short of projected need for ACTs if no additional actions are taken.
2. Limited availability of raw artemisinin is a significant barrier to both scaling up the use of ACTs and reducing their cost. In the short to medium-term, as countries in Africa begin to implement first-line drug treatment with ACTs, scaling up of all phases of production, beginning with increased cultivation of *Artemisia annua* and extraction of the active ingredient from the plant will be required to meet the increased requirement for ACTs.
3. Significant additional funding will be required by countries in sub-Saharan Africa to finance the additional costs of ACTs. Some of these costs could be covered by reallocation of funding within the health sector and by increased government allocations to the health sector. Intensive consultation will be needed with macroeconomic partners, including Ministries of Finance and Planning, donor agencies, and international financial institutions, on the reallocation of available un-programmed government funds, external assistance, and debt relief. Many countries also will need additional external financial assistance.

PROCUREMENT OPTIONS

Status of Antimalarial Drug Procurement

Currently, procurement of antimalarial drugs is highly decentralized. Countries individually procure drugs for use in public sector facilities. Private sector providers purchase drugs through existing private sector distribution networks. Government control over which products are available for purchase and the quality of those drugs is very limited, particularly in the private sector. Even with current low-cost drugs, cost is a major barrier to persons obtaining appropriate doses of effective antimalarial treatment.

The current system of antimalarial drug procurement has several limitations.

- Inadequate regulations and regulatory structures are in place to co-ordinate efforts to improve access.
- Public sector staff responsible for drug procurement often lack adequate training and have a limited understanding of the supply market.
- Government funding for ACT procurement is either insufficient or unpredictable.
- Donors have conflicting procurement regulations, although efforts to harmonize systems are underway.
- Procurement is fragmented and inefficient at provincial or district level.
- Unbiased market information is lacking.

Pooled versus Un-pooled Procurement

Given the inadequacy of the current system for procuring antimalarial drugs, alternative approaches, such as pooled procurement mechanisms, may be an important part of the solution. There are trade-offs that must be recognized when deciding on which approach to take. Un-pooled procurement provides the maximum level of country ownership and the greatest flexibility in the choice of drug and method of financing. It should be noted, though, that drug choice may be more limited in an environment that does not actively promote new drug development, as is the case today where uncoordinated buying is not stimulating drug production.

Any form of pooled procurement at supra-national level sacrifices some degree of country autonomy and possibly choice for increased leverage to reduce price through bulk purchase and better control quality. Pooled procurement mechanisms that include strengthened forecasting of demand can improve the quantity and consistency of supplies. In the case of the Global Drug Facility for TB, pooled procurement of a limited range of drugs at favorable prices has increased harmonization of national drug policies.

The status quo of un-pooled procurement for antimalarial drugs is not meeting the needs of countries. Manufacturers are not producing sufficient quantities of ACTs, because current demand is very limited and unpredictable. Such uncertainties are a barrier to manufacturers' entering the production market for ACTs. This reduces competition, resulting in higher prices for these drug combinations. Experience from other disease

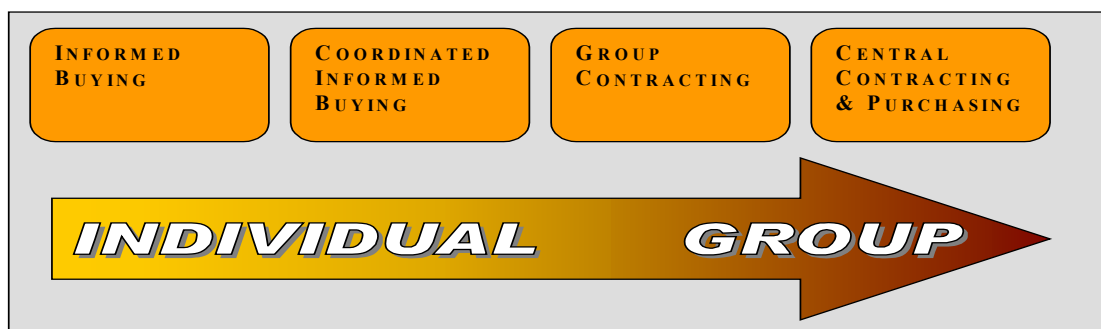
control initiatives (e.g., STOP TB and GAVI) indicates that pooling of procurement will be needed to stimulate production of ACTs, reduce cost, and improve the quality of available drugs.

Options for Pooled Procurement

Several options exist for pooled procurement. These can be divided into four major categories by the extent of pooling:

- ***Informed buying***- Purchasers share information on prices and suppliers, but purchase individually.
- ***Coordinated informed buying***- Purchasers conduct joint market research, share supplier information, and monitor price, but purchase individually.
- ***Group contracting***- Purchasers jointly select suppliers and negotiate price, with agreement to purchase from selected supplier. Purchases can be made individually or jointly.
- ***Central contracting and purchasing***- Purchasers jointly tender and contract through a global procurement agent.

A Spectrum of Options for Pooled Procurement (adapted from Elmendorf 2003)



Experience from Existing Pool Procurement Systems

The Global Drug Facility for STOP-TB

The Global Drug Facility (GDF) approach to TB drug supply bundles global pooled procurement with pooled financing and a network of partners to provide technical assistance to support drug grants. Procurement is but one component of four in the GDF framework; TB drugs are procured through a contractual partner on a centralized, pooled

basis and shipped to countries. A recent evaluation of the GDF has revealed three primary benefits of the facility:

1. Expansion of access to high quality TB drugs
2. Facilitation of DOTS expansion
3. System level benefits that have resulted in drug price reductions

The evaluation goes on to note that the combined approach of pooled financing and commodity has been key for the GDF to meet some of its goals, particularly in providing the incentives for countries to adopt the DOTS strategy and to rationalize the choice of drugs used for treatment. The key to stimulating scaled-up drug production was the ability of the GDF to predictably forecast demand.

Any effort to increase access to ACTs through a similar system would require a close examination of the goals and scope of the effort, availability and reliability of financing (new or re-allocation of existing financing), level and speed of country capacity building, and supply-side relations (price, formulations, packaging, etc.).

The necessity of linking pooled procurement to pooled financing must also be considered. If incentives are not required for countries to adopt appropriate malaria treatment policies, then pooled financing may not be necessary. Even if such incentives are required, they could also be supplied through non-centralized means.

MSH-Rockefeller Collaboration on Regional HIV/AIDS Drug Procurement

Management Sciences for Health's (MSH) has recently collaborated with the Rockefeller Foundation and key African institutions on the design of a program for Coordinated Informed Buying of HIV/AIDS-related drugs in programs of regional pooled procurement under the auspices of ACAME (an association of francophone West African countries' Central Medical Stores) and CRHCS (East and Southern Africa Commonwealth Regional Health Community Secretariat).

UNICEF-Copenhagen

UNICEF's supply division in Copenhagen has several years of experience in procuring vaccines, currently under the umbrella of Global Alliance for Vaccines and Immunizations (GAVI). Similar to the GDF, forecasting of demand was felt to be the single most important component for the success of their efforts in vaccine procurement. Approximately 25% of their effort is taken up in forecasting activities.

A Proposed Mechanism: WHO's Initiative to Establish Global MATCH System

As conceptualized by the Director General, WHO is seeking to establish a centralized drug procurement facility for key communicable diseases, including possibly malaria. Existing drug procurement activities, including the GDF and the agreement with Novartis on Coartem[®], would be integrated into this proposed facility. The purpose of this facility

would be to 1) improve the supply of core commodities for HIV/AIDS, TB, and malaria and 2) leverage commodity supply to improve other aspects of prevention and control.

Furthermore, the GMS is envisaged to address:

- Forecasting of demand
- Quality assurance
- Market stimulation (through advocacy, resource mobilization, etc)
- Intellectual property rights issues
- Technical assistance
- Monitoring and evaluation

The proposed Malaria Commodity Hub will bring together producers and buyers to improve information flow between the two to increase access to effective malaria treatment. The mechanisms of under which this facility will function have yet to be determined.

Conclusions

1. There is a need to stimulate production of ACTs

There is general agreement that the ACT production market is underdeveloped. Competitive suppliers are likely to develop in response to relatively predictable demand. There is a need for public sector action to jump-start the supply system. In addition, current and potential manufacturers should be made aware of the existing opportunities and financing available to purchase ACTs.

To stimulate ACT production, necessary steps include:

- a. Developing capacity to conduct detailed forecasting of need, demand, and available financing.
- b. Establishing international reference standards for ACTs.
- c. Systematically collecting and disseminating data on the actual prices paid for ACTs.

There also may be a need for limited investment toward developing in production capacity, which could include direct investment for upgrading or expanding existing production facilities, or financing new start-ups through mechanisms such as the IFC.

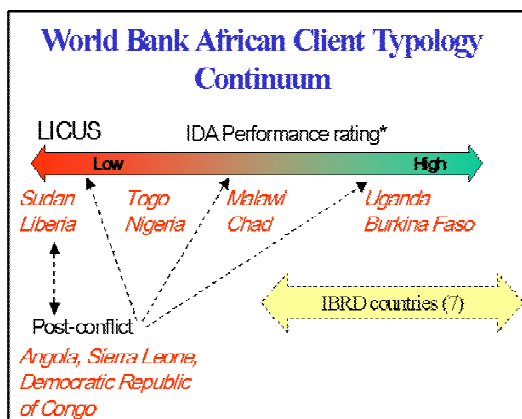
2. Pooled procurement, at global and/or regional level, is needed to reduce prices and improve drug quality and regularity of supply. Key stakeholders of RBM should develop a specific proposal on what mechanism would be best for pooled procurement of ACTs for presentation to the RBM Board. A mechanism could be modeled on the GDF.

Key Points of Agreement:

- a. “Informed Buying” and “Coordinated Informed Buying” is probably not sufficient to significantly reduce price.
- b. Any pooling mechanism should be built upon existing institutional structures.
- c. Two potentially desirable existing institutional homes are:
 - i. UNICEF- Copenhagen
 - ii. GDF- probably as part of its evolution towards WHO’s MATCH mechanism
- d. Linkage of procurement with predictable financing is likely to result in stronger stimulation of production and resultant price reductions. The nature of the linkage and its institutional arrangements merit further discussion by RBM.
- e. Some key criteria that should be considered in the design of a pooled procurement mechanism for ACTs. Such a mechanism should be:
 - i. Easy to use by countries.
 - ii. Easy to initiate and operate in existing development assistance environment.
 - iii. Capable of purchasing commodities at low price.
 - iv. Capable of creating and maintaining information on demand and incentives for multiple suppliers to enter and stay in the market, and for motivating new product development.
 - v. Capable of delivering desired level of subsidy through public, NGO, and private distribution channels.
 - vi. Capable of conveying information and incentives to rapidly and appropriately expand ACT use (particularly in children and the poor).
 - vii. Capable of conveying incentives to minimize inappropriate use of products.

FINANCING OPTIONS

Typology of Countries



* IDA Performance scores encompass CPIA, portfolio, and governance discount.

Countries' needs and modalities for external financing will depend on their level of social and economic development. The World Bank has developed a typology to categorize recipient countries into three categories: Middle Income, Low Income, and Low Income Countries Under Stress (LICUS). LICUS countries include countries with recent civil unrest (e.g., Sudan, Angola). Countries are also ranked on the performance of their public sectors into high, medium, and low performers

The type and amount of external financial assistance will vary based on these performance rankings. Financial support to high performance countries will focus on supporting governments to scale up appropriate interventions. Such an approach in LICUS countries would not be appropriate, as these governments often lack both the policy environment and the capacity to implement key interventions. In LICUS countries, investments for scaling up public health interventions may be better focused on supporting non-governmental organizations and the private sector, which often have better implementation capacity.

A Framework for an International Understanding on Antimalarial Drug Financing

In developing an international understanding on external financing of ACTs, it must be placed in the context of current trends in development assistance. Possible elements of such an understanding include:

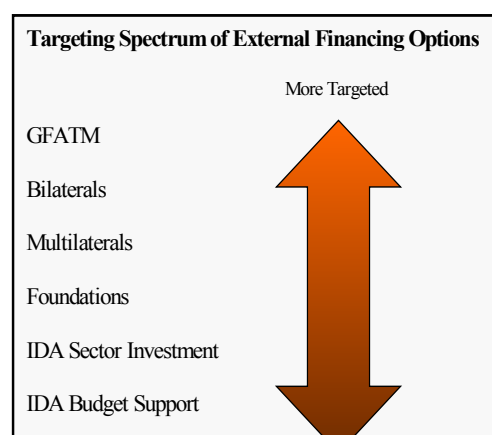
1. External financing comes from a multiplicity of sources and channels, under differing terms.
2. Recipient countries have a key role in allocating external resources. Country-level earmarking of funding by external donors tends to be illusory in effect and limits ownership.
3. New financing structures are not desirable. The preponderance and leadership of a limited number of sources should be respected.
4. The roles of individual financiers can build upon their comparative advantage(s).
5. Malaria control program planning should be integrated into overall health sector planning.
6. Official development assistance is moving towards budget support, allowing recipient countries more flexibility to establish program priorities and respond to change.

7. Opportunities exist for smaller financiers to move funds for drug purchase through larger partner agencies (e.g., GFATM, trust funds at international financial institutions, UNICEF or an expanded GDF at WHO)
8. A successful drug financing effort must include long-term actions to strengthen the supply market and reduce cost and price by means such as advance commitment.
9. Financing provided directly to multi-country programs and/or non-governmental organizations and the private sector may be required in the short to medium-term in some contexts, especially in LICUS countries.

Examining Available and Potential Financing for ACTs

Existing external financing sources, which could support scaling up of ACTs, vary greatly in certain key characteristics, including:

- The ease of access to funds by health officials. Given the variance in levels and layers of coordination between them, the ability of health officials to mobilize the sources in a timely fashion will also vary. Some types of financing, such as un-disbursed monies from credits and loans are often seen as “hidden funds”, where the path to unlocking them can be unclear, complicated, and require the efforts of a variety of recipient country stakeholders.
- Some monies, particularly those supporting the health sector at more macro levels – such as budget support and debt relief transfers – are more fungible than others.
- The degree of targeting of financial resources varies. For instance, can HIPC funds, the least targeted form of external financing, be captured for this purpose, resulting in substantial increases in financing for ACTs?
- The rules for use of funds (e.g., whether funds can be used to purchase commodities or to provide subsidies through the public or private sectors) tend to vary by source. Recent efforts to harmonize provision of aid may reduce procedural differences and fund-specific conditionalities.



An Estimation of Available and Potential External Financing for ACTs

One of the key issues facing African countries and their external partners, as they face decisions to change malaria treatment regimens to more effective and more expensive drugs, is whether the currently and potentially available financial resources will be sufficient to finance such new, scaled-up programs. To assist in answering this question, information was collected and collated from a number of sources to present data on external financial resources that are currently and potentially in future available to finance scaled up antimalarial drug programs in Sub-Saharan Africa. Numerous assumptions were made in the analysis and the data represent orders of magnitude rather than firm estimates. It is important to note that a major effort will be required at the country level to mobilize potentially available public and private resources. Some of the potentially available resources used to calculate the total potentially available can only be mobilized through a process of internal debate and reallocation at the country level by African officials responsible for health resource allocation at the macroeconomic and sectoral levels. Finally, the estimations represent an aggregate view and provide no information on financing gaps at the country level, which can only be determined in the framework of country-specific analysis.

Recent average annual total donor health commitments:	US \$ 2.8 billion
Estimated annual commitments for malaria:	Current: US \$ 540 million Potential: US \$ 870 million
Estimated annual funds available for purchase of antimalarial drugs:	Current: \$ 170 million Potential: \$ 310 million

- Different external funding sources vary in their ability to be pooled and targeted toward purchasing commodities.

Additional Options for External Financing- Issues for Further Discussion

Beyond providing external support to countries for the purchase of ACTs, other potential areas for external investment include:

- Direct support to NGOs and the private sectors at country level to establish or strengthen capacity for drug distribution, quality monitoring, etc.
- Stimulate production of raw materials to break through pricing ‘floor’, including possible development of synthetic artemisinins.
- Incentive financing and advanced commitments (one-time market stimulation or on-going stimulation).

Conclusions

1. At the global level, current resources for ACT financing are insufficient .

There are varying estimates of the finances available today to purchase ACTs in Africa. Nevertheless, there is consensus that currently available monies in some countries are insufficient to meet the current and future requirements to finance combination therapies. The long-term financial gap, however, is dynamic and will depend on price, effect of prevention efforts, coverage strategies, and production costs, to name a few.

RBM should assist countries to identify and mobilize existing sources of funding both within the health sector (e.g., central basket financing) and beyond (e.g., HIPC funds). RBM also has a key role in mobilizing additional external financing for countries where current domestic and external resources are not sufficient.

The framework for an international understanding of ACT financing, as detailed above, may help in clarifying both the short and long-term inputs required. For instance, though funding is currently a major limiting factor for ACT delivery, it may not be the key constraint in the medium to long-term (distribution capacity, for instance, may be a more formidable bottleneck). The constraints to ACT uptake merit analysis and monitoring as treatment policy is revised and implemented.

Role of the GFATM

- Donors governments must ensure sufficient contributions to the Global Fund so that new challenges such as ACT financing can be met
- Countries applying to the Global Fund should include ACTs in their proposals when an evidence-based drug policy shift is in order.
- Reallocation of GFATM funding is possible if countries decide to change drug policy to ACTs.
- The GFATM Board should examine whether alternative methods of providing finances would be beneficial in stimulating the development of production

capacity for ACTs (e.g., direct allocation of resources to an entity that would purchase drugs and supplies for Fund-supported projects).

2. There is a need to document existing ACT financing and procurement requests as well as forecast needs to stimulate the market.

Existing resources available for ACT purchase need to be identified, documented, and conveyed to industry so that existing demand is understood by all parties. An examination of GFATM proposals that include requests for ACT procurement would be one place to start. This information on current and expected spending could easily be monitored and regularly updated. In addition, as countries make evidence-based shifts in national treatment policies to ACTs, forecasting may be helpful to stimulate production and competition, as well as stimulate efforts to mobilize necessary financial resources.

A time-limited purchase commitment?

In the short-term, there is a need for a critical mass of funds to guarantee a high volume purchase of ACTs in the next few years, to stimulate the development of a competitive market for production. One estimate of resource requirements puts the need at US \$10-20 million annually over the next three years. Although there are theoretical benefits to a time-limited purchase fund, the effort and expense of establishing such an entity are large. Improved forecasting and coordination of purchasing through existing mechanisms will likely achieve the same goals.

3. Investment in drugs alone is insufficient. Support must also be directed to strengthening country's capacity to effectively deliver malaria control interventions to populations at risk.

Countries must reduce the number of people needing treatment and not getting it. An expansion of treatment coverage within on-going malaria control efforts would prepare Ministries of Health and partners to rapidly scale up ACT treatment once drug policies were changed. Support for the general strengthening of health care provision and preventive services are vital to the effective implementation of strategies to scale-up ACT use. NGOs and private sector providers have a central role to play in such efforts and should be supported.

COUNTRY-LEVEL ACTIONS

Framework for Changing Drug Policy and Implementing that Change

Determining the efficacy of current first-line treatments and alternative regimens is just one step in the process of deciding to change drug policy and then implementing that change. Several additional factors must be considered both during the decision-making process and the implementation phase. Areas that must be considered include:

1. Assessment of available financing
 - a. Availability and price of drugs in the public sector and private sector
 - b. The current role of the not-for-profit sector (NGOs, PVOs, missions)
 - c. Current sources of financing for drugs and what is the mechanism of payment
2. Impact analysis of possible scenarios when ACTs are introduced
 - a. Ability/willingness to pay (i.e., a contingent valuation survey)
 - b. Accessibility to treatment
 - c. Accessibility to vulnerable groups (i.e., children <5 years, pregnant women, the poor)
 - d. Role of the private and NGOs
3. Targeting, pricing, and subsidies
 - a. Is targeting required?
 - b. Who will be targeted (e.g., children <5 years, pregnant women, the poor)?
 - c. Who will be targeted for subsidies?
 - d. How will targeted subsidies be delivered (e.g., subsidized product, vouchers)?
 - e. What mechanisms to deliver subsidies (e.g., public vs. private sector, NGOs)?
4. Financing options
 - a. Current sources (e.g. government budget, external assistance).
 - b. New sources (e.g. taxes, user fees, external financing instruments).
 - c. Attributes (e.g. reliability of resource flow, ease of access, ease of pooling).
5. Sustainability² plan
 - a. What is the time horizon of domestic and external financing?
 - b. What is the mix, over time, of domestic and external financing?
6. Implementation Plan
 - a. Financing needs will be driven by the overall implementation plan, which will define the role and type of financing required.
 - b. Important to focus on actions needed to secure and disburse funds for ACTs.

² Sustainability as defined by GAVI: “the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis”

Drug Procurement, Financing, and Distribution: Experience from Zambia (Chirwa 2003)		
Procurement	Financing	Public Distribution
Central Board of Health (CBoH) directly using pooled health sector funds	Health Sector budget <ol style="list-style-type: none"> 1. Gov funds (pooled) 2. Cooperating partners (pooled and projects) 3. Contributions (e.g. churches) Global Fund and other global financing	Medical Stores Limited stocks and distributes (public sector only): <ol style="list-style-type: none"> 1. Health Center Kits – to rural and urban health centers (supply driven) 2. Essential drugs bulk supply 3. Other drugs (demand driven)
Global agencies on behalf of CBoH	Drug Supply Fund (DGIS, DFID, CIDA)	
Directly by non-pooling partners (e.g. JICA and health center kits)	HIPC	
Establishment of a Drug Supply Fund	Global Fund and other external	

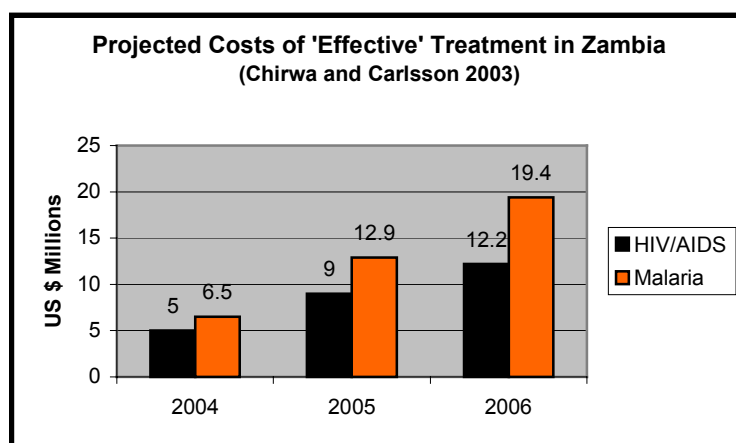
Decision-making and Policy Change: Experience from Zambia

Zambia is one of a small number of countries in Africa that has recently changed their national malaria treatment policies, which included adopting ACTs as their first line therapy. Specifically, the policy decisions based on available efficacy trials were:

- Chloroquine phased out as the first-line treatment
- Artemether-lumefantrine (Coartem®) combination therapy adopted as new first-line treatment
- Sulphadoxine-pyrimethamine (SP) to be used in the transition phase
- Intermittent presumptive treatment (IPT) using SP to be introduced for pregnant women

Managing the implementation of a drug policy change requires actions in several dimensions. In particular, one cannot neglect the political dimensions of effecting the change. To this end, several factors are essential to facilitate such policy changes:

- Promoting the change in the context of a long-term development perspective.
- Political mapping (i.e., identifying and assessing the perspectives of all stakeholders).



- Leadership and ownership at high levels in the Ministry of Health with a willingness to make bold decisions.
- Short-term resource mobilization to implement the decision (ACTs, ARVs, etc) while medium-long term financing strategies are developed.

Ensuring Access to Vulnerable Groups

Even if global efforts to reduce price are successful, the cost to consumers of ACTs is likely to be significantly higher than the cost of current first-line drugs. Cost has been and will remain a major barrier to effective treatment. Persons with malaria will frequently buy insufficient doses of drug because it is all they can afford.

Countries have attempted to address this barrier by providing subsidies at varying levels and through a variety of channels. Each approach has had its trade-offs and limitations. For example, countries that have provided global subsidies through their public sector health facilities have often been faced with insufficient supplies of drugs. Access to drugs delivered through the public sector will also be limited to those people who have physical access to these facilities.

As ACTs are introduced, countries will need to determine the most effective methods to deliver subsidies to their target population and the level of subsidy required to ensure access. A significant challenge will be how to provide subsidies through the private sector, where 60% to 80% of malaria cases are currently managed. This challenge has caused some to consider whether providing subsidies at the global level might be a more efficient approach to delivering low cost drugs in both the public and private sectors. The benefits of such an approach are only theoretical and the feasibility is questionable.

Conclusions

1. Countries must lead efforts to develop and implement rational drug policies.

There is no single prescription for successfully effecting these changes, as each country context is different. There are key issues, though, that must be addressed in every country to ensure the smooth implementation of appropriate drug policies that reach the most vulnerable.

A draft framework for effecting a change in drug policy is elaborated above and requires further review by stakeholders. This framework will be strengthened by in-depth analysis of the process of policy change and implementation in selected countries, with an elaboration of best practices.

Affected countries face a number of challenges in their efforts to rationalize malaria treatment policies. They must strive to:

- Ensure access to drugs through both public and private sectors
- Target and deliver subsidies, including through the private sector and NGOs

- Develop medium and long-term sustainability plans
 - Regulate local markets
 - Improve private sector role in drug provision
2. International partners in RBM have an important role in facilitating the process of drug policy change by providing support at various stages in the policy development, including:
- Strengthened support to countries to identify and access existing and potential funding for ACTs (and malaria commodities generally)
 - Information sharing on prices, quality, availability, supply to link market development with demand
 - Technical assistance to countries to support evidence-based policies and strategies
 - Development of mechanisms to facilitate procurement
 - Compilation and sharing of country experiences and best practices in policy change, procurement, financing, subsidies, and delivery
3. Countries will need to provide subsidies to vulnerable consumers to ensure access and appropriate use of ACTs.
- Each country must systematically evaluate trade-offs for differing levels of and methods of providing subsidies in light of its unique country context.
 - Subsidies will be required to ensure access in both the public and private sectors.
 - Further discussion and analysis is needed on the efficiency, desirability, and feasibility of subsidies provided at the global level .

RECOMMENDATIONS

Several key actions should be taken by the RBM Partnership to ensure access to high-quality, affordable ACTs in the short to medium-term.

1. A comprehensive effort should be carried out to stimulate the production of ACTs. A commitment of \$10-\$20 million per year for at least three years is necessary to stimulate manufacturers to scale up production. This could be carried out in the short term by coordinating purchases of several countries.
2. A procedure to pool procurement of ACTs should be developed, at global level (and possibly regional level, as well) which will be needed to reduce drug price and improve drug quality and regularity of supply. More will be needed than simply the sharing of information on prices and availability if costs are to be significantly reduced. This capacity should be developed within existing structures of RBM and modeled on WHO's GDF. Essential components of such a mechanism would be:
 - a. Comprehensive and continuous forecasting of country-level need, demand, and available financing.
 - b. Support to scaling-up production of raw artemisinin and strengthening production capacity (e.g., upgrading facilities to GMP standards).
 - c. Establishment of international reference standards
 - d. Quality monitoring of available products.
 - e. Coordination of financing from existing sources
3. Countries should be assisted to identify existing and new sources of funding to finance the purchase and subsidy of ACTs, including existing country resources from within the health sector (e.g., SWAP finances) and outside (e.g., PRSCs, HIPC, and governmental budget). In a number of cases, additional external financing will be needed in the short to medium term. Donors and financiers, such as the GFATM and the World Bank, can respond to country requests for additional assistance through established channels, but cannot subvert domestic decision-making processes.
4. Countries must develop strategies to expand access to malaria treatment, particularly to the most vulnerable populations and through the private sector. The provision of subsidies will be an essential component of such strategies. Each country must determine the level, target, and delivery method of subsidies, based on the country context. Innovative methods to deliver subsidies through the private sector and NGOs must be developed and deployed.
5. RBM should document countries' experiences with developing and implementing drug policy change. Best practices should be developed and promoted for procurement, financing, subsidies, and delivery mechanisms.
6. International partners must continue to provide technical assistance to countries to support evidence-based drug policies and strategies.