Costing Artemisinin-based Combination Therapy for Malaria in Tanzania

June 2005

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Mission

Partners for Health Reformplus is USAID’s flagship project for health policy and health system strengthening in developing and transitional countries. The five-year project (2000-2005) builds on the predecessor Partnerships for Health Reform Project, continuing PHR’s focus on health policy, financing, and organization, with new emphasis on community participation, infectious disease surveillance, and information systems that support the management and delivery of appropriate health services. PHRplus will focus on the following results:

Implementation of appropriate health system reform.

Generation of new financing for health care, as well as more effective use of existing funds.

Design and implementation of health information systems for disease surveillance.

Delivery of quality services by health workers.

Availability and appropriate use of health commodities.

June 2005

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Contract/Project No.: HRN-C-00-00-00019-00

Submitted to: USAID/ Dar es Salaam

and: Karen Cavanaugh, CTO
Health Systems Division
Office of Health, Infectious Disease and Nutrition
Center for Population, Health and Nutrition
Bureau for Global Programs, Field Support and Research
United States Agency for International Development
Malaria continues to be a major contributor to the burden of disease in Tanzania, with a prevalence of 33.39 percent nationally. As antimalarial resistance to sulfadoxine-pyrimethamine in Tanzania continues to grow, the government is in the process of changing its national policy regarding first-line treatment for uncomplicated malaria to an artemisinin-based combination therapy (ART). ACT, a new type of antimalarial drug combination, has proved to be effective at treating malaria and reducing malaria transmission. The PHRplus project, on behalf of the Roll Back Malaria Partnership in conjunction with the World Bank, undertook a costing study to estimate the five-year financing needs and identify financing gaps for procurement of three possible ACT combinations, Coartem®, artesunate amodiaquine (ART AQ), and Artecom™.

The Global Fund to Fight AIDS, Tuberculosis and Malaria award for malaria during the fourth round of proposals will cover the majority of the first year of public sector ACT implementation if Coartem® (with a financing gap of US$1.4 million) is chosen, or the bulk of public sector implementation for the full five-year period under ART AQ or Artecom. ACT funding must be secured for the medium- to long-term future. Financing for the purchase of ACTs is likely to come from the Global Fund, the World Bank, and the various other partner agencies.
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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT</td>
<td>Artemisinin-based Combination Therapy</td>
</tr>
<tr>
<td>ART AQ</td>
<td>Artesunate Amodiaquine</td>
</tr>
<tr>
<td>DHS</td>
<td>Demographic and Health Survey</td>
</tr>
<tr>
<td>IPT</td>
<td>Intermittent Preventative Therapy</td>
</tr>
<tr>
<td>ITN</td>
<td>Insecticide-Treated Bednet</td>
</tr>
<tr>
<td>MSD</td>
<td>Medical Stores Department</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
</tr>
<tr>
<td>NMCP</td>
<td>National Malaria Control Programme</td>
</tr>
<tr>
<td>PHRplus</td>
<td>Partners for Health Reform plus</td>
</tr>
<tr>
<td>RBM</td>
<td>Roll Back Malaria Partnership</td>
</tr>
<tr>
<td>SP</td>
<td>Sulfadoxine-Pyrimethamine</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
This study of Artemisinin-based combination therapy costing needs in Tanzania was informed by discussions with the U.S. Agency for International Development (USAID) and the World Bank in Washington DC and Dar es Salaam, the Centers for Disease Control and Prevention in Atlanta, and the World Health Organization in Geneva and Dar es Salaam.

At the country level, several government and non-governmental organizations provided input on both the costing assumptions and methodology, including the Tanzanian National Malaria Control Program, Medical Stores Department, the Tanzania Food and Drug Administration, National Institute of Medical Research, Ifakara Health Research and Development Centre, the Tanzania Essential Health Intervention Project, John Snow Inc (JSI)/DELIVER, Management Sciences for Health, Christian Social Services Council, and René Salgado (JSI).

Special thanks goes to Dennis Carroll (USAID), Julie McLaughlin and Suprotik Basu (World Bank), and Stephen Musau (Abt Associates) for their inputs.

This study was funded by USAID/Washington and implemented with the collaboration of the Roll Back Malaria Partnership.
Executive Summary

Malaria continues to be a major contributor to the burden of disease in Tanzania, with a prevalence of 33.39 percent (MARAlite 2002) nationally. Malaria accounts for 30 percent of the national burden of disease and loss of productivity in Tanzania, where the disease is endemic throughout much of the country. Growing resistance to first-line antimalarial drugs in recent years has greatly diminished the government’s ability to treat the disease. As resistance throughout Tanzania and the East African region continues to grow, the government of Tanzania is in the process of changing its national policy regarding first-line treatment for uncomplicated malaria to an artemisinin-based combination therapy (ACT).

ACT is a new type of antimalarial drug combination, based on a derivative of the Artemesia plant combined with another antimalarial drug, such as lumefantrine, sulfadoxine-pyrimethamine, or amodiaquine. Trials of ACTs have proved these combinations to be effective at treating malaria and reducing malaria transmission (Arrow et al. 2004, 22-23).

The Partners for Health Reform plus project, on behalf of the Roll Back Malaria Partnership in conjunction with the World Bank, undertook a costing study to estimate the five-year financing needs for ACT drug procurement for three possible ACT combinations: Coartem® (artemether + lumefantrine), artesunate amodiaquine (ART AQ), and Artecom™ (Piperaquine + Dihydroartemisinin + Trimethoprim). This costing study was undertaken to establish the financing needs for implementation of ACT drugs in mainland Tanzania for the period of 2006-2010. The results of this study were designed to help inform the policy dialogue on the national guidelines for treating malaria and to provide donors with information on the magnitude of the ACT financing gap. The costing estimates use a population-based malaria incidence approach incorporating the variables: population, age-specific malaria incidence, modern medicine utilization (public and private sectors), public and private sector coverage, and drug pricing.

The costing estimates yielded an average annual cost of US$53.0 million for Coartem®, US$21.4 million for ART AQ and US$25.7 million for Artecom™ over the five-year period.

The Global Fund to Fight AIDS, Tuberculosis and Malaria award for US$90.45 million for malaria during the fourth round of proposals will cover the majority (96 percent) of the first year of public sector ACT implementation if Coartem® is chosen (leaving a financing gap of US$1.4 million) or the bulk of public sector implementation (85 percent or 72 percent respectively) for the full five-year period under ART AQ or Artecom™. ACT funding must be secured for the medium- to long-term future. Financing for the purchase of ACTs is likely to come from the Global Fund, the World Bank and the various other partner agencies.

As the government plans to begin the immediate switch to Coartem®, funding is needed urgently to cover the initial US$1.4 million for 2006 needs and US$12 million and US$37.5 million

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1 Tanzania RBM Country Consultation
2 $80.7 million of the total award will be used for drug procurement.
funding for 2007 and 2008 respectively. Due to the general worldwide shortage of artemisinin, the
government should enter into immediate discussions with the World Health Organization to secure 15
million doses for 2006.

ACT availability and costs are very fluid and it is highly likely that available combinations will
increase and costs decrease in the medium term (2008 onward). As these options become available,
the government may want to consider switching to a cheaper ACT in 2007/2008 or when appropriate.
1. Introduction

Malaria continues to be a major contributor to the burden of disease in Tanzania. The population-wide prevalence of the disease is 33.39 percent (MARAlite 2002) nationally. Malaria accounts for 30 percent of the national burden of disease and consequent loss of productivity in Tanzania, where the disease is endemic throughout much of the country. Malaria control efforts take the form of prevention and treatment of malarial disease. While prevention is focused on reducing exposure to the Plasmodium parasite, treatment is focused on eliminating parasitemia from the blood stream through antimalarial drugs.

Growing resistance to antimalarial drugs in recent years has greatly diminished the government’s ability to treat the disease. In Tanzania, growing resistance to chloroquine prompted the government to change the first-line treatment for malaria in 2001 to sulphadoxine-pyrimethamine (SP), with amodiaquine as a second-line treatment. Unfortunately, due to public misinformation about the risks of side effects, many patients with fever using health centers for malaria treatment refused SP in favor of amodiaquine (Mwita 2005a, 2005b). Actual usage of SP versus amodiaquine is unclear. Current resistance rates reported by the National Malaria Control Programme (NMCP) are 24 percent for SP and 10 percent for amodiaquine (Mwita 2005b). Other sources report SP failure rates exceeding 40 percent (Reyburn et al. 2005). As resistance throughout Tanzania and the East African region continues to grow, the government of Tanzania is in the process of changing its national policy regarding first-line treatment for uncomplicated malaria to an artemisinin-based combination therapy (ACT).

1.1 Artemisinin-based Combination Therapy

Artemisinin-based combination therapy is a new type of antimalarial drug combination, based on a derivative of the Artemesia plant combined with another antimalarial drug, such as SP or amodiaquine, and lumefantrine. Trials of ACTs have proved these combinations to be effective at treating malaria and reducing malaria transmission (Arrow et al. 2004, 22-23). There is currently only one coformulated ACT: Coartem®, which is produced by Novartis. The World Health Organization (WHO) has negotiated a public sector price with Novartis, provided that the procuring government purchases Coartem® through WHO. A curative dose of Coartem® consists of four tablets four times over three days.

Several other coformulated combinations are due on the market shortly, including Artecom™ and a coformulation of artesunate and amodiaquine (ART AQ) that is being produced by Sanofi-Aventis and due in 2006. Currently, a curative dose of ART AQ for an adult is one tablet of ART with four tablets of AQ taken as one dose for three consecutive days; the ART AQ coformulation will consist of two tablets per day for three days for an adult. Generic combinations, such as ART AQ and artesunate-SP can be purchased separately or co-packaged.

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3 Tanzania Roll Back Malaria Partnership country consultation
4 http://www.essentialdrugs.org/edrug/archive/200403/msg00044.php
1.2 Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund to Fight AIDS, Tuberculosis and Malaria has been an important financing mechanism by enabling national governments to procure ACT drugs, which cost several times more than the previously used antimalarials. The Global Fund’s move toward ACTs occurred in June 2004, when a group of experts recommended to the Global Fund Secretariat that, due to growing non-ACT antimalarial drug resistance, the Global Fund should prioritize the procurement of ACT drugs (Feachem 2004). The government of Tanzania, currently in the process of changing its national malarial treatment policy, was awarded US$80.7 million through the fourth round of Global Fund proposals for the procurement of ACT drugs. Of the total award, US$64.5 million will be disbursed for the first two years, with the remaining disbursement based on performance.6

While the Global Fund malaria award will contribute to the cost of ACT implementation, procurement may remain a challenge as there is presently a worldwide shortage of artemisinin. As malaria-endemic countries begin to change their national treatment policies to ACT drugs, it is expected that the global market will respond, scaling up growing and production, hopefully by 2007. The shortage of artemisinin is most heavily impacting the production of Coartem®. ACT availability and costs are very fluid and it is likely that available combinations and overall supply will increase and costs decrease in the medium term from 2008 onward.

The World Bank, via the Roll Back Malaria Partnership, requested technical assistance from Partners for Health Reform Plus (PHR Plus) to better inform the drug selection and implementation choices faced by the government of Tanzania. The PHR Plus team has developed drug cost estimates for the switch from SP to ACTs for several drug coverage scenarios in the public and private sectors. It is anticipated that results from this costing study will directly inform the policy debate, and cost estimates will be used to secure funding for ACTs beyond the limits of Global Fund financing.

1.3 Costing Scenarios

In order to estimate the financing needs for the implementation of ACT drugs in Tanzania, several scenarios were costed. Three potential artemisinin-based drug combinations (Coartem®, artesunate amodiaquine, and ArtecomTM) were selected and each was analyzed for implementation in the public sector alone as well as in the public and private sectors with a 50 percent subsidy in the private sector.

- **Coartem®** (artemether + lumefantrine) is the only coformulated ACT approved by WHO and is currently available through WHO at a negotiated public sector price. A curative dose of Coartem® consists of four tablets four times over three days.

- **Artesunate amodiaquine** is a WHO-approved ACT that can be co-packaged. Its elements are both generics but there are some questions about growing amodiaquine resistance in Tanzania, due to use as a monotherapy. An adult curative treatment of ART AQ comprises one 200mg tablet of ART with four 200mg tablets of AQ taken as one dose for three consecutive days.

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5 All references to the government of Tanzania, Ministry of Health and National Malaria Control Programme refer to mainland Tanzania only.
6 Source: NMCP communication. Please note that the Global Fund website indicates only $76 million for ACT and $54 million in the first two years.
Artecom™ (Piperaquine + Dihydroartemisinin + Trimethoprim) is a coformulated ACT that has not yet been approved by WHO, but clinical trials are underway and approval is likely – possibly by the end of 2006. Artecom™ is one of several artemisinin-based combinations centered on Piperaquine (others include CV4®, CV8®, Artek® and Duo-Cotecxin)
2. Methodology

2.1 Estimating ACT Needs Approach

In order to estimate the financing needs to ACT drugs in Tanzania, the following population-based formula was used:

\[
ACT \text{ financing needs} = \text{Population} \times (\text{population} \times \text{annual growth rate} \times \% \text{ of relevant age group}) \times \text{febrile illness incidence per age group} \times \text{sector utilization} \times \text{coverage within sector} \times \text{public health impact} \times \text{drug price (including handling fees)}
\]

2.2 Assumptions

The assumptions used for this costing scenario are set out in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Assumptions Used in ACT Costing in Tanzania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
</tr>
<tr>
<td>Population growth rate</td>
</tr>
</tbody>
</table>
| Fever incidence in episodes per year, per age, per individual | Under 1: 5.4  
1-4: 3.8  
5-14: 1.5  
15 and over: 2.1 |
| Utilization (% of episodes treated with antimalarials) | 2006-2010: 70%*  
Public/non-profit sector  
Coartem®  
2006: 35%  
2007: 39%  
2008-2010: 42%  
ART AQ, Artecom™  
2006: 35%  
2007: 37%  
2008-2010: 39%  
Private facilities/pharmacies sector  
Coartem®  
2006: 35%  
2007: 32%  
2008-2010: 28% |

<table>
<thead>
<tr>
<th>Variables</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART AQ, Artecom™</td>
<td>2006: 35%</td>
</tr>
<tr>
<td></td>
<td>2007: 33%</td>
</tr>
<tr>
<td></td>
<td>2008-2010: 31%</td>
</tr>
<tr>
<td>Private sector subsidy</td>
<td>50%</td>
</tr>
<tr>
<td>Current yearly government spending on first-line antimalarials</td>
<td>US$3.5 million**</td>
</tr>
<tr>
<td>(estimate based on current procurement levels)</td>
<td></td>
</tr>
<tr>
<td>Public/non-profit sector coverage</td>
<td>2006: 50%</td>
</tr>
<tr>
<td></td>
<td>2007: 70%</td>
</tr>
<tr>
<td></td>
<td>2008: 80%</td>
</tr>
<tr>
<td></td>
<td>2009-2010: 90%</td>
</tr>
<tr>
<td>Public health impact (reduction of episodes) due to insecticide-treated</td>
<td></td>
</tr>
<tr>
<td>nets use and more effective antimalarials, per annum</td>
<td>5%</td>
</tr>
<tr>
<td>Private sector uptake (sales) over the five year period</td>
<td></td>
</tr>
<tr>
<td>Coartem®</td>
<td>2006: 0%</td>
</tr>
<tr>
<td></td>
<td>2007: 15%</td>
</tr>
<tr>
<td></td>
<td>2008-2010: 20%</td>
</tr>
<tr>
<td>Artecom™, ART AQ</td>
<td>2006: 0%</td>
</tr>
<tr>
<td></td>
<td>2007: 20%</td>
</tr>
<tr>
<td></td>
<td>2008-2010: 50%</td>
</tr>
<tr>
<td>WHO handling fee</td>
<td>3%</td>
</tr>
<tr>
<td>WHO freight and insurance</td>
<td>9%</td>
</tr>
<tr>
<td>Medical Stores Department (MSD) handling fee (including taxes)</td>
<td>6%</td>
</tr>
<tr>
<td>MSD distribution fee</td>
<td>8%</td>
</tr>
<tr>
<td>ACT costs (adult treatment dose in first year, including above fees)</td>
<td></td>
</tr>
<tr>
<td>Coartem®***</td>
<td>2006-2010: US$2.89</td>
</tr>
<tr>
<td>ART AQ</td>
<td>2006-7: US$1.59</td>
</tr>
<tr>
<td></td>
<td>2008: US$1.22</td>
</tr>
<tr>
<td></td>
<td>2009: US$0.98</td>
</tr>
<tr>
<td></td>
<td>2010: US$0.73</td>
</tr>
<tr>
<td>Artecom™</td>
<td>2006-2010: US$1.47</td>
</tr>
</tbody>
</table>

* The utilization of modern antimalarials is considered to be constant at 70%.

** In discussion with the NMCP it was decided not to include current government funding on antimalarials as a possible source of funds, as the funds will continue to be spent on SP and amodiaquine.

*** The dosage used for this calculation is Novartis-recommended dosage for partially immune populations.
2.2.1 Population

For each yearly calculation, the population is determined by multiplying the mainland Tanzanian population at the 2002 census by the growth rate, and then calculating the number of individuals in the designated age brackets using the population breakdown from the 2002 census (National Bureau of Statistics, Tanzania 2002).

Mainland population at 2002 Tanzania census: 33,461,849
Population growth rate: 2.3 percent

There is large variation in reported population growth rate data, from 1.9 percent (U.S. Census Bureau) to 2.9 percent (per annum; the figure used, 2.3 percent (Population Reference Bureau 2004), is a mid-range figure.

Table 2. Age Breakdown in 2002 Census for Mainland Tanzania

<table>
<thead>
<tr>
<th>Age group</th>
<th>Percentage of total population</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-12 mo*</td>
<td>2.80</td>
</tr>
<tr>
<td>13-59 mo</td>
<td>13.65</td>
</tr>
<tr>
<td>5-9 years</td>
<td>14.89</td>
</tr>
<tr>
<td>10-14 years</td>
<td>12.88</td>
</tr>
<tr>
<td>15+ years</td>
<td>56</td>
</tr>
</tbody>
</table>

* Source: Reid 2005.

2.2.2 Fever Episodes per Year

Table 3. Fever Episodes per Year (Ifakara, low range)

<table>
<thead>
<tr>
<th>Age</th>
<th>Fever episodes per year</th>
<th>Total malaria cases</th>
<th>Malaria cases treated with modern medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>5.4</td>
<td>967,915</td>
<td>677,541</td>
</tr>
<tr>
<td>1-4</td>
<td>3.8</td>
<td>3,352,910</td>
<td>2,347,037</td>
</tr>
<tr>
<td>5-14</td>
<td>1.5</td>
<td>2,742,756</td>
<td>1,919,929</td>
</tr>
<tr>
<td>&gt;15</td>
<td>2.1</td>
<td>7,548,341</td>
<td>5,283,838</td>
</tr>
</tbody>
</table>

Tanzania has three malaria transmission zones: endemic, seasonal, and epidemic. For this reason, it is difficult to determine the national incidence for febrile illness. The fever incidence rates used in the data represent the low range of incidence data from a 2002 household survey of three malaria endemic districts: Rufiji, Kilombero, and Ulanga. These data were collected by Ifakara Health Research and Development Centre, which was monitored malaria incidence in the three endemic districts over the course of several years. These data show the number of completed episodes of fever episodes in the past two weeks. Because the Ifakara data were collected in a high-incidence area, the lower estimates from this area were used when applying data to the entire country, in an attempt to account for lower-transmission areas. The higher data range for febrile illness for the past two weeks (fever either completed or ongoing) was:
Fever episodes per year (Ifakara high range):

<table>
<thead>
<tr>
<th>Ages</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1:</td>
<td>7.03</td>
</tr>
<tr>
<td>1-4:</td>
<td>4.63</td>
</tr>
<tr>
<td>5-14:</td>
<td>1.68</td>
</tr>
<tr>
<td>&gt;15:</td>
<td>2.78</td>
</tr>
</tbody>
</table>

For comparison, the 1999 Demographis and Health Survey (DHS) figures are:

<table>
<thead>
<tr>
<th>Ages</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1:</td>
<td>10.71</td>
</tr>
<tr>
<td>1-4:</td>
<td>8.68</td>
</tr>
</tbody>
</table>

### 2.2.3 Utilization

<table>
<thead>
<tr>
<th>Utilization of antimalarials:</th>
<th>70 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public sector*:</td>
<td>35 percent</td>
</tr>
<tr>
<td>Private sector*:</td>
<td>35 percent</td>
</tr>
</tbody>
</table>

Utilization refers to the number of cases of fever that are treated with modern antimalarials. This figure is then divided into utilization rate by sector.

The rate of 70 percent modern medicine utilization is derived from the 1999 DHS. The public-private breakdown of utilization is determined from a general agreement among relevant experts that there is an approximately even split between utilization in the public and private health sectors.

The impact of public sector-only distribution of ACTs is anticipated to have an effect on utilization of modern antimalarials in the private sector. It is estimated that implementing Coartem® in the public sector will result in an annual utilization increase of 10 percent for the first two years before stabilizing, increasing public sector utilization from 35 percent to 42 percent. For ART AQ and Artecom™, utilization in the public sector is anticipated to increase 5 percent annually over the first two years and then stabilizing, i.e., from 35 percent to 39 percent. The different utilization rates are a reflection of the comparatively large price differential between public and private sector prices for Coartem® when compared with the less significant prices differentials between the public and private sectors costs of ART AQ and Artecom™.

The utilization rate of 70 percent is a conservative estimate for utilization of modern medicine for treatment of fever in the context of other available data. Research from Ifakara shows 86 percent report seeking taking some action when a household member has fever, with 3 percent not necessarily modern medicine. These data are corroborated by another study conducted in the same region (de Savigny et al. 2004), which shows that among fatal illnesses in Rufiji district in children under five, 78.7 percent of cases sought modern medicine. However, due to active health interventions and access to treatment, Ifakara figures may not be representative of national health behaviors.

Because of lack of data on the age breakdown of health seeking behavior in Tanzania; utilization was assumed to be the same across age groups. Also, due to inconsistent ordering of currently used

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7 Public sector includes non-profit facilities (non-governmental organizations [NGOs] and mission).
8 The term ‘private sector’ includes private for-profit facilities and pharmacies.
9 The 1999 DHS reports the utilization of modern facilities in Tanzania as 67.5 percent National Bureau of Statistics, Tanzania, and Macro International 2000).
antimalarials in the public sector, it is difficult to extrapolate the number of SP and amodiaquine
doses consumed annually in public facilities.

2.2.4 Public Health Effect of ACTs and ITN Use

The inclusion of the public health effect is intended to reflect the public health benefits of
increasing insecticide-treated net (ITN) usage. Thus malaria control interventions such as ITNs
depress the overall number of malarial episodes per individual per year. Calculating a public health
impact at the scale of mainland Tanzania is difficult. One study (Phillips-Howards et al. 2003) has
shown that, when ITN coverage of a community reaches significant ITN coverage (above 60 percent),
there is consequently a 35 percent decrease in malarial episodes among children. There is also general
agreement that a more effective antimalarial drug treatment will reduce overall malaria incidence and
hence febrile illness, although published research on the efficacy of ACTs at low transmission is not
yet available. It is important to note, however, that the public health impact assumes widespread
acquisition and utilization of ITNs nationally, which relies on affordable distribution of nets and re-
treatment kits at the local level.

Because most ITNs in Tanzania are not permanently treated nets, and with low documented re-
treatment rates and because of a lack of information on the population-wide impact of ACTs, the
reduction in fever cases as a result of the ITNs, ACTs, and other public health intervention is
estimated conservatively at 5 percent a year, or 23 percent cumulatively over the first five years of
implementation.

Please note that this is the first time in undertaking such an exercise that a public health impact
has been used. There is a lot of debate on this subject and some will see 5 percent as conservative
while other may see it as overly optimistic.

2.2.5 Cost of ACTs

Of the three ACTs considered, Coartem® is the only one that has an established retail price (the
US$2.40 WHO-negotiated price for an adult dose in the public sector). The price for ART AQ used in
these estimates is calculated using the average price of generics on the international market. The
source of the price for Artecom™ is notes of a Task Force Meeting on Malaria Treatment Policy in
2004. The price has been adjusted (increased by US$0.20) to reflect the current artemisinin shortage
and the weakness of the U.S. dollar.

The cost of Coartem® and Artecom™ are projected to remain constant over the five-year period,
as both drugs are patented or trademarked. It is likely that a generic Coartem® could be produced ex-
patent but, for these estimates, such a scenario was not modelled. For Artecom™ the uncertainty
about its availability and approval by WHO led to employing a conservative scenario whereby costs
remain stable.

For ART AQ, the estimates assume that cost decreases over time. Sanofi-Aventis has announced
that a coformulated version of ART AQ will be available in 2006 at the price of US$1 per adult
treatment and US$0.5 per child treatment. Added to the international price of the ACTs are the
appropriate handling charges for WHO and Medical Stores Department (MSD).

None of the scenarios project an increase in the price of artemisinin in the next two years,
although such an increase is a possibility. However the actual costs of ART AQ and Artecom™ may
be higher in the short term. For Coartem®, it is anticipated that the WHO negotiated public sector price will remain but that supplies may be short.10

2.2.6 Public Sector ACT Distribution

This scenario assumes that the new ACT will be available to the public/non-profit sector at the price of current antimalarials. This reflects the current global consensus on affordability of first-line antimalarials, in that subsidies must be applied to make the new antimalarials as affordable as those currently being used.

2.2.7 Private Sector ACT Subsidy

Under this scenario, the government will make ACTs available to private facilities and Level I and II pharmacies at half of its WHO-negotiated cost. Some form of price control and verification will be necessary for monitoring. The benefit of the subsidy must be significant enough – and hence the subsidy level high enough – to off-set program or transaction costs of implementation in the private sector. The costs of ACTs to the provider at a 50 percent subsidy are listed in Table 4.

Table 4. Cost of ACTs over Five Years at a 50 Percent Private Sector Subsidy (US$)

<table>
<thead>
<tr>
<th>ACT costs @ 50% subsidy</th>
<th>Coartem®</th>
<th>AQ + ART</th>
<th>Artecom™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult dose in Year 1 (2006) (Costs include WHO and MSD handling charges)</td>
<td>$1.45</td>
<td>$0.76</td>
<td>$0.79</td>
</tr>
<tr>
<td>Year 2</td>
<td>$1.45</td>
<td>$0.59</td>
<td>$0.79</td>
</tr>
<tr>
<td>Year 3</td>
<td>$1.45</td>
<td>$0.59</td>
<td>$0.79</td>
</tr>
<tr>
<td>Year 4</td>
<td>$1.45</td>
<td>$0.59</td>
<td>$0.79</td>
</tr>
<tr>
<td>Year 5</td>
<td>$1.45</td>
<td>$0.59</td>
<td>$0.79</td>
</tr>
</tbody>
</table>

Please note that the subsidized prices would be extended to the provider or retailer; retail prices would have to be higher to provide a margin of profits for retailers and to cover handling costs.

2.2.8 ACT Coverage and Uptake

Coverage is defined as the percentage of fever cases using modern medicine that are treated with ACTs.

In the public sector, the term *coverage* is used to refer to those attending public health sector facilities who receive ACTs as a percentage of those attending public health sector facilities who receive any antimalarial.

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10 There is talk of cultivating and processing the artemesia plant in Tanzania. Besides the risk of investing into production for a product that may soon be synthesized, it is unlikely that production costs would be lower than Vietnam or China. While it may be worthwhile to produce artemisinin, the plant’s local production is not likely to have a cost implication for procurement.
For the financing projections, the ACT coverage in the public sector is estimated as shown in Table 5:

**Table 5. ACT Coverage in the Public Sector as percent of Treatments**

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>70%</td>
<td>80%</td>
<td>90%</td>
<td>90%</td>
<td></td>
</tr>
</tbody>
</table>

It is assumed that, in 2006, it will take time for ACTs to displace current first-line drugs.

The term *uptake* is used to refer to clients in the private sector who opt for an ACT as a percentage of private sector clients purchasing any antimalarial. In 2006, it is assumed that, due to global shortages of artemisinin, ACTs will not be available at subsidized prices in the private sector.11

For the financing projections, the ACT coverage in the private sector for Coartem® is estimated as shown in Table 6:

**Table 6. Coartem® Uptake (Sales) in the Private Sector as percent of Antimalarial Treatments**

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>15%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td></td>
</tr>
</tbody>
</table>

The relatively low uptake of Coartem® is due to the comparatively high subsidized drug price (US$1.45 for an adult treatment).

Uptake of Coartem® in the private sector is estimated to reach 20 percent by 2008, with 7 percent of all fever cases (or 10 percent of all modern medicine treatments) treated with Coartem® distributed through the private sector. The implementation of a private sector subsidy will increase government spending per annum on Coartem® by as much as US$10 million.

For the financing projections, the ACT coverage in the private sector for ART AQ and Artecom™ is estimated as shown in Table 7:

**Table 7. Artecom™ and ART AQ Uptake (Sales) in the Private Sector as percent of Antimalarial Treatments**

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 percent</td>
<td>20 percent</td>
<td>50 percent</td>
<td>50 percent</td>
<td>50 percent</td>
<td></td>
</tr>
</tbody>
</table>

The increase in uptake estimate is based on a subsidized price for Artecom™ and ART AQ lower than Coartem® (US$0.74 and US$0.80 for an adult treatment respectively), resulting in increased uptake. However, like Coartem®, Artecom™ and ART AQ sales would be limited to private Level I and II pharmacies only, thereby limiting the drugs’ widespread availability.

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11 The assumption is that, faced with a tight supply situation, the government would choose to supply the public sector before making the ACTs available to the private sector.
2.2.9 Leakage and Wastage

The amount of ACT loss due to ‘leakage’ from the public sector to the private sector and possibly to other countries has not been estimated. While Ifakara provides anecdotal evidence of ART AQ leakage (drugs in public sector drug packaging for sale in private pharmacies and shops), there is no accessible robust data on current leakage. Distinctive public sector packaging has the potential to limit leakage to the private sector. Also due to lack of available data, the exercise does not take into consideration the possible wastage due to ACTs’ short shelf-life of two years from production.

2.2.10 Current Global Fund Round 4 Financing

Tanzania has been awarded US$90.45 million for ACT financing in Round 4 of the Global Fund, US$80.7 million of which will be used for the procurement of ACTs. For the first two years, US$64.5 million will be available. The release of remaining funding is contingent on performance over the first two years. For costing projections, the remainder of the funds were applied in total to Year Three; however, the balance potentially could be spread over more than one year.

2.2.11 Current Government Spending on First-line Antimalarials

Current government spending on first-line antimalarials is US$35 million. This figure is an estimate, based on MSD procurement data for SP and amodiaquine. Based on conversations with the National Malaria Control Programme, these funds are assumed to be used for the continual procurement of SP and amodiaquine. The cost of intermittent preventative therapy (IPT) procurement was not accounted for separately in this estimate. No assumptions have been made about increased government funding for first-line drugs.

2.2.12 IPT in Pregnancy

SP will continue to be used for IPT in pregnancy until an ACT is certified. The additional cost of procuring ACT for IPT in the future has not been calculated.

2.2.13 Economic Costs

As this is a financial forecasting exercise and the government is unlikely to forgo current spending to meet future needs, no discount rate for future costs of money has been used and all figures are constant.
3. Financing Gap by Scenario

Table 8 shows the financing need for ACT implementation in the public and private sectors of mainland Tanzania. The public sector figures for Coartem® range from US$34 million to US$58 million per annum, with a US$7-10.6 million increase when a 50 percent private sector subsidy is added. The range for amodiaquine artesunate is a more moderate US$16-22 million, which is tempered by a lower beginning cost and an anticipated drop in drug price over the next five years. When a 50 percent private sector subsidy is added to the equation, the total cost of implementation increases by US$2.5-7 million per annum. ArtecomTM begins at US$16 million per annum, peaking at US$26 million in the public sector. The private sector subsidy increases the total cost of implementation by US$4-9.5 million per year. Note that the private sector projections for AQ ART and Artecom™ account for an increase in private sector uptake from 0 to 50 percent, while the analogous increase in Coartem® uptake in the private sector plateaus at 20 percent. The difference in uptake is a result of the relative affordability of the three ACTs costed.

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coartem</td>
<td>$33,700,905</td>
<td>$45,220,143</td>
<td>$53,772,521</td>
<td>$58,051,924</td>
<td>$66,310,703</td>
</tr>
<tr>
<td></td>
<td>$33,700,905</td>
<td>$52,116,977</td>
<td>$63,319,915</td>
<td>$68,649,238</td>
<td>$66,716,762</td>
</tr>
<tr>
<td>ART AQ</td>
<td>$15,693,608</td>
<td>$15,579,137</td>
<td>$20,098,887</td>
<td>$21,881,057</td>
<td>$21,221,105</td>
</tr>
<tr>
<td></td>
<td>$15,693,608</td>
<td>$18,501,647</td>
<td>$27,216,150</td>
<td>$29,268,897</td>
<td>$28,444,978</td>
</tr>
<tr>
<td>Artecom</td>
<td>$16,269,350</td>
<td>$20,995,883</td>
<td>$23,938,638</td>
<td>$26,079,963</td>
<td>$25,295,909</td>
</tr>
<tr>
<td></td>
<td>$16,269,350</td>
<td>$25,084,735</td>
<td>$33,049,790</td>
<td>$35,548,647</td>
<td>$34,547,952</td>
</tr>
</tbody>
</table>

* Because of varying uptake rates between ACT choices in the private sector, all scenarios are not based on the same number of treatment doses.

Table 9 shows the financing gap under different ACT implementation scenarios. The financing gap for Coartem® ranges from US$1.4-56 million in the public sector, reaching US$68 million when the private sector subsidy is added.

The financing gap for ART AQ and Artecom™ does not appear until later in the projections. Global Fund monies cover the ACT financing needs for amodiaquine artesunate almost completely in the public sector with a shortage of just under $14 million total. The ART AQ gap when the private sector is added is $7 million in 2009 and $35 million in 2010. The financing gap for Artecom™ does not appear until 2009, when there is a $7 million gap in the public sector and a $29 million gap when the private sector is included. In 2010, the gap increases to $32 million for the public sector and $35 million for the public and private sectors combined.
Table 9. Financing Gap Scenarios (US$)*

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coartem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities</td>
<td>$1,450,905</td>
<td>$12,970,143</td>
<td>$37,542,521</td>
<td>$57,612,650</td>
<td>$55,883,794</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>$1,450,905</td>
<td>$19,866,977</td>
<td>$47,089,915</td>
<td>$68,179,038</td>
<td>$66,259,798</td>
</tr>
<tr>
<td>ART AQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities - 35% Public</td>
<td>($16,556,392)</td>
<td>($33,227,255)</td>
<td>($29,358,368)</td>
<td>($7,477,311)</td>
<td>$13,743,794</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>($16,556,392)</td>
<td>($30,304,745)</td>
<td>($19,318,595)</td>
<td>$6,800,302</td>
<td>$35,245,280</td>
</tr>
<tr>
<td>Artecom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities - 35% Public</td>
<td>($15,980,650)</td>
<td>($27,234,767)</td>
<td>($19,526,129)</td>
<td>$6,553,835</td>
<td>$31,849,743</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>($15,980,650)</td>
<td>($23,145,915)</td>
<td>($6,326,125)</td>
<td>$29,222,522</td>
<td>$34,547,952</td>
</tr>
</tbody>
</table>

* The financing gap is not calculated cumulatively; the annual financing gap represents the needs for that year only.

As a result of the financing gap, the consequent shortages in ACTs expressed in adult doses are listed in Table 10.

Table 10. Adult Dosage Gap

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coartem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities</td>
<td>473,483</td>
<td>4,232,633</td>
<td>12,251,501</td>
<td>18,944,472</td>
<td>18,376,248</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>473,483</td>
<td>6,483,323</td>
<td>15,367,166</td>
<td>22,402,764</td>
<td>21,772,126</td>
</tr>
<tr>
<td>ART AQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>11,746,833</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5,812,224</td>
<td>30,124,171</td>
</tr>
<tr>
<td>Artecom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public/NGO facilities</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4,156,415</td>
<td>20,198,975</td>
</tr>
<tr>
<td>All facilities and pharmacies</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>18,532,802</td>
<td>21,910,168</td>
</tr>
</tbody>
</table>
3.1 By Scenario

3.1.1 Coartem®

The financing gap for Coartem® (Table 8) illustrates the dramatic increase in financing needs, following the depletion of Global Fund monies in 2008. The financing gap (Figure 1) in the public sector begins in 2006 with a deficit of US$473,483. While the private sector subsidy for this projection covers 50 percent of the cost of ACT drugs, anticipated uptake of ACTs is estimated to be quite low, resulting in a small percentage of overall financing needs going to the private sector to purchase a relatively small number of treatments.

*Figure 1. Financing Gap* for Coartem, 2006–2010

*The financing gap accounts for available resources through the Global Fund Round 4 award for ACT procurement, but does not take into account possible government contributions of other donor resources.*
3.1.2 Artesunate Amodiaquine

The financing needs for artesunate amodiaquine will be largely covered by Global Fund financing (Figure 2). The exception to this arises in the private sector subsidy in 2009, at which point the financing requirement will be approximately US$7 million.

Figure 2. Financing Gap of ART AQ, 2006–2010
3.1.3 Artecom™

The Global Fund monies cover the cost of Artecom™ until 2009, when a deficit appears in both the public and private sectors (Figure 3).

**Figure 3. Financing Gap for Artecom™ 2006–2010**

![Figure 3. Financing Gap for Artecom™ 2006–2010](image)

3.2 Sensitivity Analysis

A sensitivity analysis was performed to estimate the difference in funding requirements as a result of an under- or over-estimation of ACT financing needs. To consider this, the rate of increase in public sector utilization under the Coartem® scenario was increased sharply. In the moderate scenario, which is outlined in the Coartem® scenario earlier, the utilization rate increases 10 percent annually (35 percent in 2006 to 42 percent in 2008) for the first three years and then levels off. In the second scenario, which shows a substantial increase in utilization, utilization rate climbs five percent annually (35 percent in 2006 to 50 percent by 2009) until 2009 and then plateaus (Figure 4). As a result of the increase in utilization, there is a consequent increase in financing needs of US$1.5 million to US$9.3 million per year (Table 11).

**Table 11. Sensitivity Analysis for Coartem® in the Public Sector with Changing Utilization Rates**

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public/NGO facilities with moderate increase in utilization</td>
<td>$33,700,905</td>
<td>$45,220,143</td>
<td>$53,772,521</td>
<td>$58,051,924</td>
<td>$56,310,703</td>
</tr>
<tr>
<td>Public/NGO facilities with substantial increase in utilization</td>
<td>$33,700,905</td>
<td>$46,770,443</td>
<td>$56,814,537</td>
<td>$67,025,665</td>
<td>$65,641,702</td>
</tr>
</tbody>
</table>
The difference in utilization illustrated is a scenario that could potentially occur as a result of having more effective antimalarials available at an accessible price in public health facilities. This sensitivity analysis is intended to demonstrate the difference in cost magnitude that changes in initial assumptions can make.
4. Policy and Implementation Implications

The policy and implementation of the change to ACTs present several challenges:

- There is a current global shortage of artemisinin. This has the potential to prevent timely procurement of the required number of ACT doses in the short to medium term. The shortage may delay the initial introduction of ACTs and could prevent full coverage of the private sector. It is likely that, as a result of the global shortage of Artesunate and the financing gap, the amount of Coartem® available in 2006 will not cover all of Tanzania’s public sector needs. The government should plan for a phased roll-out of Coartem® targeting the areas of the country with the greater resistance to SP.

- The shelf-life of Artesunate is two years from production, making overstocking of the drug a financial liability.

- If the government chooses to distribute ACTs through the public sector alone, there is a danger of significant leakage to private sector and to neighboring countries. Also if the ACTs are only available in the public sector, it is expected that sector-wide utilization of public health facilities will increase. An increase in utilization in the public sector may push the limits of any spare capacity, impacting staff morale and possibly leading to poor quality health care.

- Initially, the public sector-only options will make ACTs available to treat about half of the fever cases. Estimates show that, due to procurement challenges and implementation scale-up concerns, full coverage implementation will be difficult to achieve in the first year. The other half of fever cases in the public sector is likely to continue to be treated with current first-line drugs (SP and amodiaquine), resulting in a decreased public health benefit of ACT introduction.

- Government provision of subsidies to the private sector would increase the accessibility of ACTs; however, there is a large transactional cost associated with this. A subsidy for the private sector would necessitate fixed retail prices and a monitoring system to ensure private vendor compliance. The government would most likely be responsible for the cost of monitoring and enforcement. Even at 50 percent subsidy, Coartem® still would remain out of reach to the majority of Tanzanian (US$1.45 adult dose).

- Coartem® would be the presumed ACT for two to three years. As conditions (supply and prices) change, other ACTs may become more attractive (cheaper). Is the government prepared to change first-line drugs for malaria twice within a five-year period?
5. Conclusions and Recommendations

Following the dissemination of the PHRplus financing figures, the government of Tanzania decided to postpone changing the national malaria treatment policy to name ACTs, however plans have been made to begin procuring Coartem®. The funding available from the Global Fund for AIDS, Tuberculosis and Malaria will cover about the majority of the need of the public sector (including non-profits) for 2006, leaving a financing gap of US$1.4 million. This will deplete the entirety of the Global Fund award’s first disbursement.

Therefore, if the government wants to have national Coartem® coverage in the public sector in 2006, it needs to identify an additional US$1.4 million for ACT procurement immediately. As there have been no plans made to apply for additional funding through the fifth round of the Global Fund, at the present time there is no firm plan of how the financing gap will be funded. An alternative strategy is to roll out Coartem® progressively, initially targeting the areas with the highest resistance to SP.

While the Global Fund financing will contribute to the cost of Coartem® implementation, there is presently a worldwide shortage of artemisinin and the government should enter into immediate discussion with WHO on securing 15 million doses for 2006. As the need for antimalarials continues to rise, the global market will respond to the current artemisinin shortage, making ACT drug procurement easier.

ACT availability and costs are very fluid and it is highly likely that available combinations will increase and costs decrease in the medium term (2008 onward). As these options become available, the government may want to consider switching to a cheaper ACT in 2007/2008 or when appropriate.
Annex A: References


Mwita, Alex. 2005b. Personal correspondence with Dr. Alex Mwita, program manager at National Malaria Control Program.


