Affordable Medicines Facility – malaria

RBM AMFm Task Force

Second interim report on progress against outstanding AMFm implementation challenges

Summary of the meeting in Geneva

19 August 2008

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Introduction

In April 2008 the Board of the Global Fund to Fight AIDS, TB and Malaria agreed to ask the Global Fund Secretariat to prepare to host and manage the AMFm as a business line within the Global Fund:

- based on the AMFm design and business plan set out in the Secretariat Report to the Policy and Strategy Committee (GF/PSC9/03); and
- subject to final approval at the Eighteenth Board Meeting of a policy framework and implementation plan that incorporates the principles set out in their Decision Point and "offers practical solutions, in consultation with technical partners, to remaining technical issues (including identification of strategies to maximize access to ACTs by the most vulnerable and poorest and ensuring patient safety)."

The Global Fund Board acknowledged the work and recommendations of the RBM Task Force on the AMFm design, as endorsed by the RBM Executive Committee, and joined the RBM Executive Committee in asking the RBM partnership and the AMFm Task Force to continue to contribute to the development of the AMFm and to pursue all options to maximize access (including targeting the poorest through free distribution of ACTs through public and NGO channels).

In May 2008, the Roll Back Malaria Partnership (RBM) Board acknowledged the first interim report of the RBM AMFm Task Force on outstanding implementation challenges and requested the Task Force to continue to work with the Global Fund and UNITAID on outstanding implementation challenges.

The RBM AMFm Task Force conducted intensive further work on four implementation challenges:

- Country preparedness
- Resource mobilization for technical assistance
- Evaluation
- Reaching the poor

The RBM AMFm Task Force met in person in Geneva on 19 August 2008 for a full day conference hosted by the RBM Secretariat to discuss the recommendations.

This Second Interim Progress Report includes the conclusions from the meeting and aims to update the Global Fund AMFm Ad-Hoc Committee on the work undertaken to address the outstanding issues flagged at the Seventeenth Global Fund Board meeting.

The RBM Partnership Board has repeatedly declared its support for the creation of an Affordable Medicines Facility – malaria (AMFm) to be implemented in accordance with the technical design it endorsed in November 2007. With its expected effect on the affordability of ACT treatment across all sectors, the AMFm represents an important component alongside others in the comprehensive response to malaria.

I. Country preparedness

Initial proposal

This work looked at how to identify which countries are ready and hence eligible to be included in Phase 1 of the AMFm. The approach follows four key steps:

1. Creation of a long list: A preliminary set of objective criteria are proposed to be applied to all malaria endemic countries. This led to a long list of 25 potential Phase I countries. These criteria are based on data provided by the WHO Global Malaria Program and WHO Regional Malaria Advisors, and are:

- Estimated moderate-to-high malaria mortality (>0.1/1000/year)
- Multi-year experience with large scale deployment of ACTs (before 2007)

2. Mapping of additional country characteristics and potential overall restrictions: The following elements amongst others also need to be considered in selecting the eligible countries for inclusion in AMFm Phase I:

- A potential risk of a global shortage of artemisinin during Phase I of the AMFm, in case ACT demand exceeds the available API supply in 2009
- The impact of a country selection on the amount of leakage of subsidized ACTs from participating to non-participating countries
- The complexity of simultaneously managing implementation in multiple countries meeting the proposed criteria in case of high ACT requirements
- Inclusion of countries outside Africa with problems of artemisinin tolerance
- The preparedness level of countries
- Relative private sector versus public sector distribution levels within countries.

3. Country consultations: The countries that will be selected through the above process with RBM Taskforce guidance will be consulted in October to assess their willingness and preparedness to participate in Phase I of the AMFm. The process of engaging countries is still to be determined but will be led by the Global Fund.

4. Creation of final shortlist: The list of countries obtained after country consultation will then be presented to the November Global Fund Board Meeting for their consideration.

Discussion

The preliminary criteria recommended by WHO were seen as objective and appropriate. Participants suggested additional criteria could include identifying countries with malaria grants that potentially qualify for the Global Fund's Rolling Continuation Channel (RCC); countries with health insurance schemes and countries undertaking a Malaria Indicator Survey or another household survey that covers malaria treatment behaviour in 2009.

Scoring, weighting and ranking country preparedness was discussed but not felt appropriate as a selection mechanism. There will also be qualitative factors and country preferences to take into account. It was noted that the decision on which countries could access AMFm in Phase 1 might also be affected by the resources available, both in terms of availability of the artemisinin active pharmaceutical ingredient and in terms of financing for the co-payment.

The Ad-Hoc Committee will discuss a short list on 15 September.

Consensus recommendations

- The long list of 25 countries is based on objective/scientific criteria.
- Availability of funds for the co-payment may impact on the number of countries that can access AMFm Phase 1
- API availability and possibility of shortage to be further assessed
- Options for Global Fund Board to decide how many of the 25 countries will access AMFm in Phase 1:
    - Start with first group of most-prepared countries in April 2009 and progressively allow other countries from the long list to start AMFm during Phase 1 (strong preference of the RBM Task Force)
    - Start with first group of most-prepared countries in April 2009 and then wait until end of the Phase 1 period (Nov 2010) to allow other countries from the long list to join
- Other criteria to be considered to determine country preparedness include:
    - Countries doing a Malaria Indicator Survey or other household surveys such as MICS, DHS or ACTwatch surveys in 2009
    - Countries with malaria grants approved or under consideration for Global Fund Rolling Continuation Channel funding
- A template / guidance should be created for those who will carry out country consultations so that countries get standardized information
- Regional groupings should be considered in order to minimize cross border leakage of low cost ACTs

II. Resource mobilization for technical assistance

Initial proposal

Four options were presented for coordinating technical assistance (TA) for the development and implementation of effective roll-out plans:

- Funds transferred directly to government or Global Fund Principal Recipient
- Block grants awarded to relevant international partners (e.g. UNICEF, WHO)
- RBM partner(s) appointed to manage a TA fund, using various partners
- Competitive selection of a consortium to provide technical assistance

Criteria for identifying a suitable TA coordinator could include: i) ability to quality assure TA provided, ii) minimum conflict of interest, iii) ability to disburse fast and responsively, and iv) ability to evaluate performance of TA providers.

This sub-group had also discussed the importance of ensuring that resources for supporting interventions are made available to countries in a timely way, synchronised with the provision of ACTs. The Global Fund proposal to find ways to make funds available rapidly for AMFm preparation, even before grants are signed, was welcomed. Partners are hoping that this is a pragmatic approach that can actually be delivered by the Global Fund.

In the sub-group CIDA had been arguing for creation of a separate financing channel within AMFm to finance supporting interventions, including free distribution of ACTs through public and NGO channels. One option would be that donors to AMFm be required to contribute a percentage of the funds towards supporting interventions. This way, existing GF funds would not be drawn away from other programmes. Other

members of the sub-group did not see the benefit of an additional channel with earmarked funds for particular supporting interventions, when these can already be funded through existing grant mechanisms of GF and others. Nor is it clear that all potential donors to AMFm would want to provide additional funds in this way.

Discussion

Option 3 was preferred by the Task Force. The Task Force felt that RBM Harmonization Working Group (HWG) is a good resource to manage a TA fund using various partners and should be asked to consider this role.

The RBM Executive Director and Secretariat confirmed that the Harmonization Working Group is a robust body with many partners that can be mobilized, including the RBM sub-regional networks and Procurement and Supply Chain Management working group. HWG works with partners at country level and should identify what technical support can be supplied by in-country partners. Specifications for TA support should be formulated to identify the skills required, and HWG could expand its consultant list to add additional skills if necessary. HWG is already working on business plans for malaria with countries and could incorporate AMFm planning too.

Asked about the HWG capacity to take on this additional role, RBM Partners involved in the HWG indicated that provided the TA fund is adequately financed the HWG would be able to do so.

The availability of TA and how to access support will need to be defined clearly and communicated to the countries, including what will be provided at a country level and what will be provided at a global level. Short and long term technical assistance may be considered.

For AMFm application development the TA would most likely be ‘pushed’ i.e. a team would go to the country to support the principal recipient in its application. For implementation support a ‘pull’ mechanism would be preferable i.e. countries would ask the central coordinator for specific technical assistance.

Resources need to be mobilized quickly so that TA can be provided to the shortlisted countries that intent to apply for AMFm Phase 1 immediately after the Global Fund Board decision in November. The proposed deadline for countries to submit AMFm applications is 21 January 2009, aligned with Global Fund Round 9. Countries will be allowed to submit their AMFm application as either an Annex to Round 9 if they are applying for Round 9, or as a standalone application if they are not applying for Round 9.

Consensus recommendations

- The Harmonization Working Group should be used as a mechanism to coordinate technical assistance to countries. Other partners not included in the HWG can be brought in to provide technical assistance where necessary.
- The Global Fund is planning to visit countries to assess their interest in participating in AMFm Phase 1, coordinating with RBM partners wherever possible. These visits could be used to identify the types and timing of technical assistance countries need to develop roll-out plans.
- Meanwhile partners at country level should start discussing and preparing for AMFm with country stakeholders, coordinating it with round 9 preparation as appropriate and ensuring country ownership.

- Funding for technical assistance to facilitate the development of roll-out plans will need to be mobilized quickly. The amount needed for this should be determined and funding identified. In addition funding will be needed for technical assistance to support implementation.

III. Evaluation

Initial proposal

- M&E indicators focus on assessing changes to patterns of ACT ‘access’ and ‘use,’ following MERG inputs and earlier Task Force work[1].
- Countries have leadership in conducting M&E. They will need to submit an M&E plan as part of their roll out plan, based on the overall M&E framework for AMFm. This should as far as possible use existing data collection mechanisms.
- An Independent technical evaluation should be commissioned by the Secretariat, to be conducted between December 2009 and November 2010.
- Red flags will focus on ‘direction of change’ rather than specific threshold values.

Discussion

As malaria is seasonal, the baseline data gathering will need to occur at the same time of year as the data gathering for the final evaluation.

Suggestions were made to strengthen the core indicators put forward by the MERG:

a) Measure price at the first line buyer level rather than the manufacturer.
b) Compare the median cost of ACTs relative to CQ, SP and artemisinin monotherapies (rather than or as well as a wage rate).
c) The indicator on extent of ACT stock outs should have a comparator; recommended this is the extent of disruption of stock for other products at public and private health facilities
d) Measure the proportion of children getting ACTs vs. non-ACT antimalarials vs. antipyretics by source (public and private sectors).

There was a suggestion to evaluate the quality of the advice consumers get to measure adherence by vendors and caregivers to guidelines. Additional indicators require additional tools which has implications for funding and timing.

The Independent Evaluator should be contracted by the Global Fund as soon as possible to ensure the baseline information is collected. It was suggested that not all countries need to cover all aspects of the evaluation: while all Phase 1 countries should track core indicators, countries could determine additional indicators to answer additional questions.

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[1] Core indicators for AMFm identified by MERG: 1) Cumulative percentage mark up between retail median unit price and manufacturers unit price for full course of ACTs; 2) Median cost to patient of full course of ACT relative to daily minimum wage for a government unskilled worker; 3) Proportion of providers reporting no disruption of stock of ACTs for more than 1 week during the previous 3 months

Consensus recommendations

- The terms of reference for the Independent Evaluation contractor should be developed as soon as possible
- Core indicators developed by the MERG should be modified based on the feedback of the Task Force
- Data collection tools need to be identified
- Ongoing monitoring throughout Phase 1 should allow countries to correct and change course during roll-out of AMFm
- Fair comparators for tracking performance with regards to equity will be needed (i.e. as well as monitoring access to ACTs by SES quintile, look at access to other health services, medicines or bed nets by quintile)
- Evaluation does not need to be the same in all countries, but core indicators should be standardized
- Complement existing processes and data collection plans in countries

IV. Reaching the poor

Initial proposal

The sub-group updated the evidence paper on reaching the poor, prepared guidance for countries applying for AMFm on ways to reach the poor and identified operations research (OR) priorities. The papers are attached as Annexes to this document.

The guidance paper gives options for interventions to reach the poor. It has been designed to assist countries in preparing roll out plans. As there is no one solution on how to reach the poor, countries are likely to use a mix of approaches. The paper sets out the most promising approaches and emphasizes the importance of Operations Research (OR) to evaluate the effectiveness of interventions targeting the poor. The paper has received substantial inputs from sub-group members and from countries at the RBM Country Consultation in Abuja 5-6 August 2008.

Countries will be expected to explain how they plan to roll out AMFm in ways that reach the poor. The key recommendation from the options paper is to ensure that interventions and services in country that are already used by and targeting the poor include ACTs e.g. health units in poor areas and services targeting poor groups, and that IEC messages are targeted to poor groups. Access can be improved if there are free services (including free distribution through public or NGO channels) or if there are waivers for the poor or for under 5s and pregnant women.

Countries may also adopt one or more of the other options covered in the paper including e.g. incentives for wholesalers to ensure ACTs are widely stocked in the commercial private sector used by the poor. Options for extending geographic coverage where other services are not reaching through Community Health Workers and contracting for services are also discussed.

Operations research (OR) questions identified by the group include gathering data for planning the interventions to expand access to the poor: Where do the poor get treatment? How do they choose providers? What prices do they pay? Who is not getting treatment and why?

OR can also be used to evaluate how AMFm affects the price and availability of ACTs, and whether ACTs reach the poor:

- How widely are ACTs available? Which measures work to avoid stock outs?
- What are ACT prices in different settings? What helps keep prices down?
- How many people access ACTs by quintile? Which providers do they use?
- Where there is free distribution of ACTs, does this reach the poor?
- What is the quality of ACT treatment from different sources? How have interventions such as provider training influenced this?

Additionally there are a number of outstanding questions around how well Community Health Workers (CHWs) are reaching the poor and how to increase their effectiveness:

- Does provision of ACTs through CHWs lead to improved outcomes in terms of reaching the poor? Do CHWs actually reach the poorest with ACTs and other interventions?
- What makes interventions most effective at a large scale? What are the lessons from experience in selection, training, retention, sustaining drug supplies, and incentives for CHWs?
- Can mobile technologies be used to improve communications and data collection by CHWs? At what cost?

The authors led the discussion around learning from experience, and suggested that there should be an OR coordination body that disseminates findings and can also provide technical support and Quality Assurance to the OR. Who is best placed to take on such a role, what support would be required and whether this should be for all AMFm-related OR, not just for additional interventions to reach the poor remain outstanding questions.

Discussion

In 2006 there was very limited use of ACTs at the peripheral level, with reported coverage of less than 5%. WHO sees the role of AMFm being to eliminate financial constraints.

Participants noted that definitions of who is poor varies across countries. The authors defined the poor as the lowest 60% of the population in socio-economic terms. Many countries are aiming for 80% coverage by 2010 to reach the Scaling Up For Impact (SUFI) targets, so this will need to include coverage of the poor.
The TDR model of a selection committee that evaluates OR proposals was suggested as a model for an OR coordination body. OR should influence policy decision-making in how useful current efforts are for reaching the poor, so there will need to be a feedback mechanism to countries rolling out AMFm in Phase 1.

The consensus was that the papers were well researched and that they highlighted the difficulty all countries and all programs face in reaching the poor. AMFm will not resolve all those difficulties but it is part of the solution. The recommendation was to start Phase 1 and build on the results of OR as they become available.

Consensus recommendations

- Countries already use a mix of different strategies to reach the poor – any additional efforts should complement and/or improve on these strategies. Build on what is happening in countries already.

- Use in-country consultations as an opportunity to find out what the priorities with regards to reaching the poor are - more bottom-up than top-down
- Encourage countries to include operational research in their country roll-out plans
- Ensure technical assistance emphasizes the need to plan and budget for operational research in roll-out plans
- Appoint a coordination body to gather information from operational research, disseminate findings via a website, and provide quality assurance and technical advice where needed.

Conclusion

The RBM AMFm Task Force should continue to engage with the Global Fund Secretariat and Board process and give technical guidance when necessary. Sub-group 1 on country preparedness should continue to work on additional indicators, ranking and narrowing down the long list through country consultations along with the GF team. Sub-group 2 on resource mobilization for technical assistance should come to a final recommendation and define requirements for technical assistance. Sub-group 3 on evaluation needs to review the M&E framework and tools and the draft terms of reference for the external evaluation contractor before the November Board. Sub-group 4 should finalize the papers attached here as Annexes. A Subgroup 5 is created with focus on PSM bottlenecks, demand forecast and API availability.

Annex 1

Options for Reaching the Poor with malaria treatment

Note linked to the application form for AMFm

Draft 4 September 2008

Prepared by the AMFm Task Force sub-group on reaching the poor.

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1. Purpose of the options note

The Affordable Medicines Facility for malaria (AMFm) is an initiative to increase access to effective malaria treatment for people in endemic countries. By making the Artemisinin Combination Therapies (ACTs) available at a much lower price, more people will be able to afford them. Through the AMFm, affordable ACTs will be available in both public and private health sectors where people, including the poor, seek treatment; thereby increasing access for the poor.

A review of the evidence on whether the poor have access to malaria treatment and the different approaches that may increase access by the poor was carried out by members of the RBM Task Force from February – July 2008 (RBM 2008). The paper summarising the evidence can be found at [http://www.rollbackmalaria.org/partnership/tf/globalsubsidy/Reaching_poor.pdf].

This review of evidence found that some of the poor have access to malaria treatment in the public and private sectors, including NGOs and for-profit providers. As with other health problems, some of the poor are not accessing treatment at all. Countries are implementing various strategies to increase access to ACTs, including making ACTs readily available through the public health system, in some cases for free; expanding the numbers of community health workers and providing them with ACTs to distribute; and some pilot schemes which provide private drug stores with subsidised ACTs so that they are more affordable.

However, there was limited evidence on the best approach in reaching the poor in malaria treatment. This is partly because many of the studies did not collect information on beneficiaries by socio-economic group. It also reflects the findings of wider studies that there is not an easy answer on what works: different approaches can work in different places, and there is not one universally successful approach. Rather, interventions need to be designed to fit with the service concerned and country context, and an intervention's success depends on its design and implementation (World Bank, 2005).

Since the available evidence is not strong enough to determine which interventions are the best and most cost effective to reach the poor, this note provides some of the most promising options, with some of the lessons learnt in applying them, for countries to consider. It was developed by technical partners under the auspices of the RBM Task Force for AMFm and is intended for national malaria control programmes and their partners who are developing roll out plans for introducing AMFm.

In the application form for AMFm, countries are asked to explain how they intend to enable and encourage increased access to ACTs by the poor and vulnerable groups. Countries will probably include several different approaches to reaching the poor, in order to maximise coverage. This note may be useful in developing the roll out plan and application, but it is not compulsory to include approaches discussed in this document. Countries can also refer to existing plans that are part of their malaria control programme and grant applications, and to wider strategies to increase access to health care by vulnerable groups.
Section 2 provides suggestions about how countries can consider whether and where the poor access treatment for malaria. Section 3 summarises some options and more detail on each is in annex 1. Given the limited evidence on interventions that are successful, cost effective and sustainable in reaching the poor, countries are also encouraged to evaluate and research their efforts in this area. Section 4 sets out some of the priorities identified for operational research.

2. Where are the poor accessing malaria treatment and why?

A starting point for developing strategies and interventions to increase the poor's access to ACTs is an understanding of where the poor currently obtain treatment for malaria.
Based on various countries' data, people seek malaria treatment from varied sources including public sector clinics and hospitals; non-profit and faith based services; and the for-profit private sector including private doctors, or nurses, pharmacies, drug stores and general shops. In some countries there are village or community health workers, usually supported by the public sector. Use of the private sector to access malaria treatment is typically much higher than for other types of treatment such as TB. Coverage, in terms of how much different socio-economic quintiles are accessing treatment, varies from country to country. Furthermore, the evidence shows that the poor use all the different providers. Therefore, in order to target the poor and vulnerable groups, subsidised ACTs need to be made available and affordable across the range of providers.
As a basis for prioritising interventions, individual countries should look at the pattern of treatment seeking behaviour in more detail. Options include:

- Data on where people seek treatment for fever by socio-economic status (SES) from household surveys such as Demographic and Health Surveys (DHS), Multiple Indicator Cluster Surveys (MICS) and Malaria Indicator Surveys (MIS).

- Further analysis may be needed to link the survey data to the socio-economic groups of the respondents and to analyse it by region, urban versus rural, etc.

- An analysis of poverty carried out for national purposes (including development of poverty reduction strategies) should provide useful data on the distribution of poverty in geographic, urban/rural and social/ethnic terms.

- Some health surveys or broader household surveys have explored the choice of treatment provider. This data needs to be reviewed as a basis for planning, including to look at the barriers for those who are not accessing treatment. This may help to identify which strategies are most likely to increase uptake in different settings; i.e., is the main barrier the price of drugs, distance and travel cost to services or knowledge of appropriate treatment? This information would help in prioritising supporting interventions.

If data on sources of treatment by socioeconomic group is not available, it could be built into the forthcoming household surveys as well as the plans for monitoring and evaluation of the AMFm and related operations research. The use of household surveys, possibly supplemented by qualitative research, can be helpful to find out who uses which services and who does not access treatment at all. This research can be part of the roll out plan.
The findings from these analyses should help identify the types of providers people use in rural areas and hence which providers need the training and supplies of ACTs. It will also identify who is not currently being reached with existing treatment sources, where they are located, and the barriers that need to be addressed to enable them to access effective treatment.

3. Options for reaching the poor

There is no magic bullet for reaching the poor. This note presents some options and encourages countries to conduct operational research that monitors who is benefiting from subsidised malaria treatment, and how to improve interventions so they enhance utilisation by the poor in a sustainable way. Countries are encouraged to implement a mix of options that complement one another, in order to reach different vulnerable groups and locations (for example, different approaches for the urban poor versus remote rural populations).

As noted above, the AMFm's core objective of reducing the price of ACTs should increase access across socio-economic groups. Effective communication about the effectiveness of ACTs, their price and appropriate use and provider training will help to ensure greater uptake. These core interventions to raise consumer awareness, train providers and monitor the impact should be included in country roll out plans and application forms. These interventions all need to be implemented in ways that are 'poor-friendly' – see the box below.

Making roll out plans for the AMFm poor-friendly
Are the types of providers that the poor use allowed to sell ACTs?
Are there several wholesalers and distributors able to buy the low cost ACTs, so there will be competition that will help keep prices down?
Are the providers used by the poor receiving training on ACT use?
Will faith based organisations and NGOs have easy access to the low cost ACTs?
Is the packaging easy to use but also not too bulky for small providers to keep in stock?
Are the media, messages and languages in communication campaigns targeted to reach poor families?
Are we monitoring the socio-economic status, age and gender of those with access to good quality ACTs?

In addition, it is recognized the lowest SES groups will be harder to reach and, therefore, extra efforts will be required to ensure they have access to affordable ACTs. Strategies to increase coverage of the poor could include the following approaches:

- Ensure that interventions and services used by and targeting the poor include ACTs
- Get ACTs out through the commercial private sector used by the poor, e.g. in rural areas (see also TDR 2006).
- Extend geographic coverage where other services are not reaching

A summary of options and issues is given below, with further discussion in annex A
.

Option	**Issues to consider**
Ensure that existing interventions and services used by and targeting the poor include ACTs for malaria treatment	
a. Ensure health services that the poor use have staff trained on ACT use, regular supplies, supervision etc.	Identify poor districts and poor areas within districts, and prioritise these for training and deployment of trained staff. Enable mission (faith based) and other NGO services to access training and ACT supplies, in areas where they serve the poor. Explore ways to overcome practical difficulties in maintaining drug supplies to rural facilities and community health workers. Explore the ability of providers to provide correct diagnosis and correct

Option	Issues to consider
	treatment
b. Identify services that target the poor and vulnerable groups and make sure they supply ACTs	Where NGOs are funded or contracted to deliver health services to target groups, build free or low cost ACT provision into their service package and performance measures. Add malaria treatment to targeted services (such as services for orphans or in slums) and identify ways to ensure drug supplies are sustained for these services.
c. Provide free services (free distribution in the public and/or NGO sectors)	Requires additional long term financing to cover the gap left by removal of fees and the increased uptake once services are free. Decision should be part of wider health sector financing strategy. Removes one of the major barriers to access by the poor.
d. Exempt the poor or children under 5 and pregnant women from paying for services (free distribution to target groups)	Requires funding for facilities to cover the costs of fees waived and the costs of increased uptake of services. Exempting malaria treatment or providing only the ACTs for free may or may not be enough to stimulate use. Waiving fees for pregnant women and children under 5 avoids the need to assess individuals' poverty status and the stigma of a waiver for the poor.
Get ACTs out through the commercial private sector used by the poor, especially in rural areas	
e. Provide incentives for the private commercial sector to distribute ACTs especially through more remote, rural outlets	Volume discounts offered by manufacturers would provide an incentive to maximise availability and sales. There is not much experience of this approach in developing countries for pharmaceuticals sold through non-pharmacy outlets, so need for careful research on how best to make it work.
f. Set suggested retail prices for ACTs	SRP needs to be promoted and advertised to have an effect; might need to set (and advertise) different prices for children and adults [to add]
g. Social marketing with a branded product and demand creation	Can include both demand side (information) and supply side (price, product and place) interventions. [to add]
Extend geographic reach to communities not accessing services	
h. Expand Community Health Workers to cover under-served communities	Define a clear and focussed set of services for CHWs to provide (not just for malaria). In addition to training, CHWs need some form of remuneration, continuing supervision, and supplies. This requires continuing funding and effective links with facility based health services, and makes this challenging to scale up.
i. Contract providers to cover under-served areas or populations	Contracts for primary health service delivery can rapidly increase coverage and, if appropriate performance indicators and monitoring systems are included, increase outreach to poorer groups.

Other approaches may be explored at country level, although at present there is little evidence of their ability to increase access to malaria treatment among the poor. These include:

- Franchising or accreditation of drug stores or private health providers. These arrangements aim to enhance the quality of services among the accredited providers or stores, and the providers receive benefits such as marketing in return for agreeing to quality standards. There are few examples at a large scale in malaria endemic countries. There is limited published evidence on how well they reach the poor and what evidence there is gives a mixed picture (in one case the better off benefited most; in another there was no association with income) (Patouillard et al, 2007). It would be important to

design an intervention with an evaluation alongside to see whether the poor benefit.

- Providing ACTs to drug stores for them to distribute for free. This approach is being tested currently on a small scale in Kenya, in nine shops that already operate with a franchise approach that includes training and supervision, but has not been tested on a large scale. The early Kenya experience found increased ACT uptake from the shops, with 9% of those accessing ACTs using this channel, while 86% of those accessing ACTs got them from public facilities (also for free). Further study is needed to determine whether the poor are indeed accessing the ACTs through this channel.

- Vouchers for poor families to access treatment. Vouchers have been provided for insecticide treated nets on a large scale in Tanzania, but they have not been tested for malaria treatment. A voucher scheme for ACTs would require a way to select those who should have vouchers, deliver vouchers to them when needed, and to reimburse providers. These mechanisms involve substantial administrative costs and complexity, and in Zanzibar the voucher scheme was abandoned in exchange for free distribution.

Funding for these interventions

Countries can apply for funding for efforts to target the poor through the normal grant mechanisms, including Global Fund grants for malaria, World Bank Booster grants, the US President's Malaria Initiative or as part of broader support to strengthen the health system and reduce child mortality. These interventions can be included in the country roll out plan for introduction of the AMFm, or form part of the broader plan for extending health/malaria services to the poor. The Global Fund welcomes grant proposals that will increase access for the poor and improve equity. [This can be updated if additional funding sources are identified]
Countries are encouraged to include in their grant applications requests for funding for operations research to measure and improve the impact of interventions.

Monitoring and evaluating progress with reaching the poor

Countries are strongly encouraged to put in place mechanisms to monitor that they are actually implementing the planned interventions and whether they have been successful at reaching the poor. This can be an integral part of the M&E plan for the AMFm at country level, but there needs to be a particular focus on whether the various strategies and interventions for reaching the poor have been implemented, and how to improve them.
It is suggested that countries should define clearly who is responsible for monitoring implementation and impact in this area. [It is suggested that there is a question on this in the application form] Core information on whether the interventions and approaches are working can come from household surveys (whether these are specific for malaria or wider in scope). Additional information may come from operational research, as discussed below.

4. Priorities for Operations Research

Operational research (OR) will be critical to provide scientific evidence for malaria control/ACT programs and to improve their quality, equity, impact and our learning. The AMFm provides a unique opportunity to build research into existing plans for scaling up ACT rollout and reaching the poor. Evidence gathered from this

operational research can be expected to strengthen the AMFm (i.e. course correct) as it moves forward and provide necessary insight into more general and essential global health delivery knowledge.

Where possible, this OR should build on existing mechanisms. For example, in terms of financing, the Global Fund already encourages inclusion of an OR component in grants. Also, there are numerous programs to increase access to ACTs already underway, and many in the planning stages, that could benefit from an OR component.

The table below highlights some of the key OR questions that have been identified in the process of reviewing the evidence on reaching the poor and could be included in planning for OR. Annex B gives some more details and comments on these OR areas.

Suggested priority research topics on reaching the poor

Type of research	Key research questions
Data for planning interventions to expand access to the poor	Where do the poor get treatment currently? What influences their decisions on choice of providers? What prices do they pay? Who is not getting treatment and why?
Evaluation of how AMFm affects the price and availability of ACTs, and whether ACTs reach the poor	How widely are ACTs available in public facilities, NGOs, CHWs, private shops in urban, small trading centres and remote settings? Which measures to ensure supplies and avoid stock outs are working? What are the prices of ACTs in different settings? Which measures help to keep prices down? How many people are accessing ACTs by socio-economic group? Which providers do they use? Where there is free distribution of ACTs, how far does this reach the poor? What are the barriers to uptake? What is the quality of ACT treatment from different sources (in terms of timeliness, appropriate dosage, etc)? How have interventions such as provider training influenced this?
Evaluation of how well CHWs are reaching the poor and how to increase their effectiveness	Does provision of ACTs through CHWs lead to improved outcomes in terms of reaching the poor? Do CHWs actually reach the poorest with ACTs and other interventions? What makes interventions most effective at a large scale? What are the lessons from experience in selection, training, retention, sustaining drug supplies, and incentives for CHWs? Can mobile technologies be used to improve communications and data collection by CHWs? At what cost?

Additional topics for the AMFm OR priority list but not really under reaching the poor – [need to move them to another list/document] include:

Type	Research questions
Monitoring the safety of ACTs and emergence of resistance	What is the actual and perceived safety profile of newly-introduced ACTs when they benefit from large-scale deployment? What is the impact of large-scale ACT deployment on parasite resistance patterns?
Evaluating the impact of diagnostics on the quality of treatment	How can diagnostics be introduced and how cost effective are they?

Annex A Description and some experience of the options

a) Ensure the health services the poor use have trained staff, regular supplies and supervision

Most countries already have plans to expand access to ACTs through the public health system. Typically, there are already plans that include ACTs in the essential drug list and the package of essential services delivered at primary care level. Many countries have started to roll out ACTs through developing the public sector medicines supply systems (logistics, transport and distribution), alongside training for health workers and IEC to the community on the efficacy of the new drugs and appropriate treatment for children. The not-for profit sector or mission services are often included in these plans. These are clearly important avenues in enabling access to ACTs for all income groups.
In looking at how to ensure that ACTs will reach the poor, it may also be useful to consider:

- How well will the services in poor districts or regions be covered? Will they be prioritised to get the training, logistics and IEC activities related to ACTs? These may include NGO services and community health workers.

- Are there faith based health providers and other NGOs that are particularly good at reaching the poor or serving poor areas? How will they be able to access the low cost ACTs?

- Are there broader health systems improvements planned that will benefit those areas? For example, research for some countries shows that the facilities in poorer areas have fewer qualified staff and less reliable drug supplies. Are there efforts to increase deployment and improve drug distribution in such areas? Will ACTs be included in the efforts to improve drug supplies?

b) Identify services that target the poor and vulnerable groups and enable them to supply ACTs

Many countries have established programmes or projects targeted to vulnerable groups. Examples include contracts with NGOs to deliver health services in slum areas or grants to community based organisations or mission services to deliver home based care to AIDS patients or support to orphans. Ensuring that these services incorporate malaria treatment with ACTs would increase access for poor and vulnerable groups.
Through the AMFm, ACTs will be much cheaper for these projects or programmes to buy, or the drugs could be provided for free by the public sector. Extra efforts may be needed to ensure organizations in the non-profit sector have appropriate information and training in use of ACTs. In addition, there may be scope to build the prompt use of ACTs and access by the poor to services into these programmes' performance indicators.

c) Providing treatment for free

There is evidence from some countries that provision of treatment for free increases uptake by the poor. Experience in Uganda showed that when user fees were removed, utilisation increased. Facility based surveys showed increases of 55% in outpatient use for referral hospitals and 77% for health centres, two years after user fees were removed. For villages near the health centres, the greatest increase in utilisation was among the poorest group (Nabyonga et al, 2005). This was confirmed by analysis of household surveys, which showed that utilisation of public health

services by the poor was substantially higher in 2003 (after the removal of user fees) than 2000 (up from 23% to 33%). The non-poor also increased service use and both groups also made more use of private sector services over the period (Xu et al, 2006).
In Zambia, when fees were removed at rural facilities, facility based data showed an increase in use by over-5 age groups of 55%, (the increase in patients under 5 years was only 7% as they were already given free services) (Masiye et al, 2008). There was a greater increase in uptake in poorer areas, but there is not yet data to show whether the poor are making more use of services.
The experience also shows that it is essential to ensure that there is adequate funding available to sustain the provision of services, including drug supplies, after fees are reduced or removed. The increase in service use requires sustained higher funding levels and more drugs reaching the facilities. If drugs are not available, or waiting times are excessive, utilisation is likely to decline again. In Kenya, when user fees at dispensaries and health centres were reduced substantially, utilisation initially increased, by around 60%. However after three months, utilisation fell to around 20 to 35% above levels before the reduction of fees. A review identified that this reflected shortages of drugs in the facilities, due to unreliable delivery of drug kits, and long waiting times for services (MOH Kenya, 2005). In Uganda, the level of use fluctuated and this was attributed partly to drug stock outs. There is also a risk that informal fees replace formal ones.
The removal of user fees is a major policy decision that should be considered in the context of broader health financing strategies. It requires careful planning to assure continued funding availability at the periphery and should be built into national health plans, rather than malaria specific initiatives. The impact of such changes on access by the poor and the poorest should be monitored.

d) Where fees are charged, give waivers to the poor or to young children so they do not have to pay.

Many countries that have user fees or charge for treatment have introduced waiver and exemption arrangements to increase access for certain groups. These may be service specific exemptions e.g. free TB treatment, free immunisations, or waivers for individuals such as for the poorest or for children under 5 and pregnant women. Although there has been significant success in the areas of free TB treatment and free immunizations, it is a common finding in many low income countries that waivers and exemptions are not always applied as intended.
A review of experience in seven low and middle income countries found that coverage of the poor with waivers in low income countries was extremely low (Bitran, 2003). A critical lesson from experience is the importance of providing sufficient and timely funding to replace the income that the provider would otherwise have received. For example, in Ghana, funds were meant to be provided by the public budget to cover the costs of treating the poor; however funding was uneven and often delayed, and the waivers were often not given in practice.
The review also highlighted the importance of clear criteria, process and guidance for assessing who is eligible for waivers; effective publicity on who is eligible, and support for non-fee costs of seeking treatment. The identification of the poor can be done in various ways – for example in Cambodia, there are 'Health Equity Funds' administered by non-government agencies that identify who is eligible for waivers from user fees and fund their health care and associated travel and food costs. They have mainly been used for referral hospital care. They have been shown to increase hospital admissions, especially by the poor, and can be well targeted to the poor (Annear et al, 2006). They do however have significant administrative costs.
There are examples where payments by better off patients allow facilities to offer free or much cheaper services to the poor (e.g. the LV Prasad Eye Institute in India). However experience of waiver schemes in the public sector suggests there are

usually insufficient incentives to rely on this as a way to ensure widespread access. Hence the design of exemptions and waiver systems need to consider the incentives and how the free services will be funded.
There is insufficient evidence to determine whether exemption from charges for malaria treatment alone is an effective option. Recent experience in Mali suggests that providing free anti-malarial treatment for patients in a cost-recovery system is not enough to increase the rate of use (MSF, 2008). In a project there, medicines and diagnostic tests for malaria were provided free of charge to children under 5, or at very low prices, leaving in place consultation fees and treatment fees for other conditions. Results after a year showed that attendance rates at health centres remained low. In a second phase of the project, all health care for the under 5s and for pregnant women with fever was made free, and utilisation increased radically. It is hard to generalise from one project, and the response will depend on implementation issues such as the amount of publicity about the changes in charges, but it does suggest that removing fees for malaria treatment may not on its own achieve intended results.
Waiving fees for children under 5 is easier to manage, as it does not require assessment of who is poor, nor is there stigma for people to apply for the waiver. However the need for extra funding arises: if fees are waived for a substantial number of service users, additional funds and drug supplies will be needed to replace the revenue and cater for increased demand.

e) Provide incentives for the private commercial sector to distribute ACTs through rural outlets

Why are supply chain incentives needed?
The AMFm will rely on established public and private sector channels to distribute subsidized ACTs; however, an alignment of incentives in the distribution channel is important to ensure that ACTs are distributed to remote areas in sufficient volumes and at a price affordable by all income segments of the population.

Economic analysis (Yadav and Ongola 2007) and experience from pilot subsidies confirms the challenge of distributing subsidized ACTs to peripheral areas. The Government of Tanzania and the Clinton Foundation ACT subsidy pilot in two rural districts has found that only 38% of stores in remote areas versus 80% of stores in more densely populated areas were stocking the product at the time of a five-month data collection (Clinton Foundation and GOT, 2008). Anecdotal evidence from district/ regional officials and the national distributor suggest that distribution to more peripheral areas is limited due to wholesaler disincentives, among these: (i) long distances and poor road conditions to peripheral areas; (ii) limited capital of retail outlets to purchase when the distributor delivers; (iii) lower demand in rural areas.

The analysis by Yadav and the Tanzania pilot experience suggest that a wholesaler incentive could play a useful role in encouraging distribution of ACTs to remote areas.

Studies from several malaria endemic countries have found that a small number of importers/ wholesalers dominate the anti-malarial market. If properly incentivized, this market structure creates the opportunity for importers/ wholesalers to influence stocking, distribution, and pricing downstream.

What other examples exist for supply chain incentives?
In 2005, as part of a five-year partnership between the Australian government and the Pharmacy Guild of Australia, a central pool of AUS$150 million was established for direct payments to wholesalers who supply the full range of medicines listed under the Pharmaceutical Benefits Scheme to urban and rural pharmacies. To be

evaluated for use of funds, wholesalers must submit data on medicines stocked and the rural/ urban pharmacies to which they distribute (Bertelsmann Stiftung, 2007).

Research also indicates that in the consumer product market, manufacturers maintain control over pricing by establishing a suggested retail price (SRP). Wholesalers and retailers that comply with the SRP receive “market development funds” for product promotion and/ or investment in facilities. Pilot subsidies in Senegal and Tanzania demonstrate that in most cases, when an SRP is applied to private sector ACTs, the patient pays the SRP (IRD, 2007, Clinton Foundation et al 2008).

Approaches to incentives in the supply chain for enhancing reach of subsidized ACTs

An incentive system to ensure that importers and wholesalers stock and distribute ACTs widely and at suggested price can be structured in different ways. Eligibility criteria to access the incentive must be established. These criteria should be developed with stakeholders and national malaria programs, and can comprise willingness to share information, agreement to provide quarterly reports, acceptance of periodic monitoring visits, and demonstrated GWP compliance.

An incentive can be applied based on different models, among them:

1. <u>Rural uptake:</u> Eligible wholesalers receive incentives for selling to a target number of rural-designated outlets; for the percent of rural-designated outlets among the customer mix; or for the percent increase in rural-designated outlets based on reported customers from previous six months
2. <u>Overall treatment access:</u> Eligible wholesaler receives rebate if the overall access (or access by a specific population segment, e.g. children under five) to ACTs increases in the specified region/ in the entire country

The applicability and choice of the best model requires operational research in each geographical context.

Challenges and next steps

Sales related incentives exist to some extent in the private pharmaceutical sector in developing counties, but it has not been adopted before as an intervention encouraged by the public sector to increase coverage to target groups. [*check with PSI – is something like this used in social marketing*]. Thus, there is limited experience with applying such mechanisms and initiatives will need to be tested and evaluated. In Zambia there are already plans to test this approach alongside introduction of low priced ACTs.

When considering the application of an incentive, several potential risks emerge. For example:

- Incentives may lead to further market concentration in wholesale business and less competition
- Reporting on sales volume or geographic coverage is inaccurate and thus targeting benefits of the incentive are not realized
- Wholesalers sell to non-approved importers/ wholesalers in order to increase volume; non-approved importers/ wholesalers will not have the same mandate to maintain low prices for the customer
- If the public sector becomes involved in managing such an incentive, and requires extensive reporting or access to records, this may deter participation by some key players.

Methods to mitigate these risks must be developed. In addition to these risks, there are unanswered questions regarding the design of the incentive:

- Technical and economic feasibility of receiving accurate baseline and ongoing information from wholesalers regarding volume sold and geographical reach.

- Economic feasibility of ascertaining overall/ vulnerable group-specific treatment access data, by region, on a regular basis. Who would conduct the assessment and how much would it cost?
- Who implements and manages the subsidy – ideally it would be handled within the private market.

f) Set suggested retail prices for the subsidised ACTs

To come

g) Social marketing

To come

h) Expand the coverage of community health workers

Community health workers bring prevention and care closer to communities, especially in the face of shortages of qualified health workers. CHWs can undertake various tasks, including case management of various childhood illnesses (eg, malaria, pneumonia, etc) and delivery of preventive interventions such as ITNs, promotion of healthy behaviour, and mobilisation of communities. Several trials show substantial reductions in child mortality, particularly through case management of ill children by these types of community interventions. CHWs come from the community they serve, and have some training but not professional qualifications.
A recent review of CHWs finds useful lessons, as well as gaps in knowledge on how to make them effective at large scale (Haines et al, 2007). The lessons include:

- Evidence that in some settings, with appropriate support and training, CHWs can improve child health outcomes and provide adequate treatment of malaria. However, the quality of service they provide is not always good. They are not a simple or cheap solution in contexts with weak health systems.

- Community participation in selection and monitoring of CHWs by the community is important. Another review (Lehmann et al, 2007) finds community ownership is key.

- The remit of CHWs should not be too wide – they perform better with a focussed set of roles and services. They can be good at following protocols for service delivery.

- CHWs need to receive some form of remuneration, which will require long term financing. Almost no examples exist of sustained community financing of CHWs. Without some incentives there tends to be very high rates of attrition.

- Availability of drugs and costs of travel to collect them are key determinants of the effectiveness of CHWs.

- Supervision is important – relying on written guidelines is insufficient. However, sustaining support supervision is often a weakness in practice.

- The relationship between CHWs and formal health services has a major impact on CHW effectiveness. Efforts are needed to ensure they recognise each others' value and roles, and avoid rivalry or distrust.

One issue is whether free distribution is necessary in order to reach the poorest. Experience from Kenya on bednet (ITN) distribution (Noor, 2007) found that free

mass distribution combined with subsidised nets distributed through clinics was effective in increasing coverage of children in the poorest families. Following two free distribution campaigns in 2006, use of nets by children under 5 reached near equality between the least poor and most poor in the study groups (66% in both poorest and least poor quintiles). Among the poorest group, 37% were using nets from mass distribution, while 24% were using nets from clinics. This experience with bed nets provides an indication of the potential of free distribution to improve equity.

However there is not clear evidence for ACTs on this. Experience with use of CHWs to improve access to ACTs was reported in a recent multi-centre study that covered four study sites (Ajayi ey al, 2008). Coverage of malaria episodes with ACTs through CHW distribution ranged from 57% to 75%. Prices of ACTs varied by study site, ranging from free (Uganda) to 0.30 US$ (children aged 36-59 months in Nigeria). The coverage level achieved was not associated with the price of ACTs. Note that the study did not look at how much the poorest groups benefited, so this needs further study for ACTs.

There is a combination of poverty and gender in this issue – as the people most vulnerable to malaria are women and children. Since most community health workers are women, this may make services more accessible for mothers to have a female health worker nearby who can correctly diagnose and dispense treatment, and advise on proper treatment and adherence.

There is still much to learn including the extent to which CHWs actually reach the poorest and how better to target inequities. Large scale CHW programmes should include research/evaluation to show their impact and cost effectiveness, to identify whether and how they reach the poorest, and to identify the reasons for successes and failures.

i) Contracting non-Government providers

Contracting non-Government providers to provide services in areas that are under-served has been introduced in various countries. The contract may be with NGO (non-profit) or private for profit providers, and the contracts can be for the provider to manage and run the services, or to take responsibility for managing public sector services.

A review of 10 contracting experiences for primary care and nutrition services in low income countries found that impressive improvements can be achieved rapidly (Loevinsohn et al, 2005). Benefits were achieved in terms of improved quality as well as increased coverage. The experience shows contracting can increase coverage even in poor, remote areas.

The contract can be used to spell out what services are expected to be delivered and to whom – for example, reaching the poor, and performance-based payments made accordingly. Cambodia's experience showed that when service delivery contracts explicitly included targets for reaching the poor, contractors were able to greatly improve health services for the most marginalised groups. Coverage of the poorest 20% with 8 health interventions went up from below 15% to over 40% in two contracted districts. They were better than government services at reducing inequities in immunisation, ante-natal care, deliveries in health facilities and outpatient utilisation. Thus it is important to include specific indicators for reaching the poor, as well as for malaria treatment, in such contracts.

The decision to contract primary health services to non-government providers can be controversial, and needs to be taken in the context of wider planning for services. It may be easier to do so where governments recognise they are failing to provide services, such as in the most remote districts, in urban slums and in post-conflict countries. There should also be scope to incorporate explicit objectives for reaching the poor with malaria treatment into any existing contracts (as discussed above).

Annex B Suggested areas for Operations Research (OR)

Knowledge Gaps	Questions	Comments
Data for planning interventions to expand access to the poor		
1. There is limited analysis showing where individuals from different SES go for treatment, what treatment they get and why they do or do not seek treatment. Some of this may be available in existing surveys such as DHS and MICS, but not fully analysed. Better understanding of why the poor do not access treatment would help identify interventions; is it distance, cash availability, etc?	Who are the poor and most vulnerable groups in the country? Where do they live? Where do the poor get treatment currently? What are the factors that influence their choice of provider? Who is not getting treatment and why?	Start by reviewing existing data sources for countries (DHS, living standards surveys, etc) to see if further analysis is needed. Incorporate relevant questions into planned household surveys. Determine whether in-depth studies on decision-making are useful. If so, could compare malaria with other health problems, and treatment with prevention.
Evaluation of how AMFm affects the price and availability of ACTs and whether ACTs reach the poor		
2. Once low priced ACTs are available, how widely are they used by the poor and the poorest? Are the ACTs affordable to the end buyer?	Are the poor accessing ACTs? Where are they getting them and at what price? At what prices are the ACTs sold in different settings?	Monitoring of prices through price surveys and uptake by different SES groups through household surveys needed. Qualitative research could be added to understand reasons.
3. Evidence review showed studies looking at impact of mass distribution through public sector facilities of ACTs have not considered who benefits by SES group.	Who benefits and who is left out from scale up of ACT provision in the public and NGO sectors? Why are some groups left out, even when services are free? Which measures and strategies are effective to broaden uptake?	This can likely be looked at by research linked to existing plans for scale up, of malaria control and possibly other services. Check whether M&E plans include data for assessing SES. May need additional research in some countries.
4. How many retailers and informal providers working in poor areas or with poorer clientele will stock subsidised ACTs and if not why not?	What are the incentives, barriers and issues facing the providers used by the poor in stocking ACTs? What is the influence of interventions such as incentives, suggested retail prices and packaging on these providers?	Qualitative research with providers accessed by the poor
5. In looking at who gets treatment, should also look at quality aspects – which drug, timeliness (within 48 hours of onset of illness), duration of treatment, dosage, and see how interventions impact on this.	What lessons can be learned from training, packaging and public education interventions on how to improve quality of treatment?	Include quality aspects in other studies.

Knowledge Gaps	Questions	Comments
Evaluation of how well CHWs are reaching the poor and how to increase their effectiveness		
6. There is renewed interest in the potential contribution of community health workers (CHWs) for improved child survival, but the introduction of large-scale programmes for CHWs requires evaluation to document the impact on malaria morbidity by SES, cost effectiveness and to elucidate factors associated with success and sustainability.	Does utilization of CHWs or community-based distribution of ACTs lead to improved outcomes and increased penetration in terms of reaching the poor? Which specific CHW training or interventions are likely to be most effective? If CHWs do better with specific roles, which ones and how many with a given level of training? Role of community drug sellers? What factors and policies increase recruitment of CHWs and reduce attrition? Can mobile technologies be used to improve communications and data collection with CHWs? What are the associated costs? What is impact and how cost effective is CHW provision of RDTs alongside ACTs? Lessons from CHWs providing other treatment e.g. for ARI as well?	Could compare free distribution (with CHWs being incentivized through other ways) to distribution with cost-recovery (possibly with waivers for the poorest). Outcome measures could be: a) degree of penetration by quintile; b) satisfaction and retention of CHWs; c) continuity of ACT supplies; d) child mortality

Knowledge Gaps	Questions	Comments
7. Surveillance of the safety of ACT and of its potential effect on parasite resistance patterns must be undertaken to monitor the impact of large-scale deployment. A sufficient number of surveillance systems must be in place, in a variety of countries, to enable appropriate monitoring of safety and resistance development. [This needs to move to another document]	What will be the actual and perceived safety profile of newly-introduced ACTs when they benefit from large-scale deployment? What will be the impact of large-scale ACT deployment on parasite resistance patterns?	New ACTs will be introduced in malaria-endemic countries with limited safety data from clinical trials, and no pharmacovigilance data from developed countries. Good quality data collected in "real life situations" must be generated to anticipate potential rumors and controversies on the safety of ACTs. Population subsets such as pregnant women and young children will deserve particular attention. Existing pharmacovigilance systems need to be strengthened, and, in addition, innovative data collection methods need to be designed. "Resistance selection pressure" will be especially high where only one ACT is used nationwide. Resistance monitoring systems must be strengthened to assess the impact of the "selection pressure" exerted by widely deployed ACTs on the potential development of resistances.

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Annex 2

Review of the evidence on access to malaria treatment among the poor

in the context of the proposed Affordable Medicines Facility for malaria (AMFm)

Paper prepared for the RBM AMFm Task Force

Draft 4 September 2008

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Summary

The purpose of this paper is to summarise the evidence and issues around how the poor and the poorest groups in malaria endemic countries access malaria treatment, in order to consider how far the AMFm can be expected to reach the poor and ways to enhance its impact on the poor and the poorest groups. The poor are defined here to include the lower 60% of the population in terms of socio-economic status (SES), and the poorest as the worst off, within the lowest 20%.

Key findings from the literature on who has access to treatment include the following:

- Malaria cases and mortality from malaria are concentrated in poor countries, hence tackling malaria is a priority for the poor;

- Among poor countries, access to treatment is very variable; the better performers achieve around 60% access to anti-malarials for children under 5 with fever (in 2005 or 2006); other countries have lower levels of treatment (although the case for treatment of all fevers with anti-malarials depends on the pattern of malaria in the country).

- In terms of equity in access, all SES quintiles have some access to treatment, but the proportion from poorer groups getting treatment tends to be lower than the better off. District level studies indicate that the differential is very variable, and sometimes there is little difference across the lower 4 quintiles.

- There is limited data on treatment quality by SES group, but what there is suggests the better off get better quality care (more effective anti-malarials, full course etc).

- All SES quintiles use the private sector for malaria treatment e.g. 75% of treatment is from the private sector in Nigeria, with no difference among SES groups.

- The better off tend to make more use of public sector hospital care than the poor.

- Home based fever management with community health worker distribution of ACTs is being rolled out in various countries. There is little data on how well it reaches the poor. One study in Uganda that looked at whether it reaches the poor found that it was twice as successful in reaching the least poor SES quintile (50% reached) compared to the lower quintiles (20-25% reached). Further work is needed to identify how to ensure such efforts are reaching the poorer groups and how to scale up and sustain such programmes.

- There was success in adding malaria treatment and other interventions alongside distribution of ivermectin in areas where the community already manages onchocerciasis control. However, sustaining the supplies of anti-malarials in the community was a problem.

- The pilot scheme to provide subsidised ACTs through small drug shops in 2 districts in Tanzania has produced early results. Within five months, almost half of the consumers purchasing anti-malarials bought ACTs in the districts where low price ACTs were available (compared to 1% before the pilot started, and 0.1% in the control district). There were more purchases by least poor than from the poorest customers but in one district the proportion from poorer groups had increased substantially over time. The monitoring also

showed that the low price was passed on to customers, and there was no evidence of 'price gouging'. Prices in remote rural shops were no higher than in trading centres with more competition; this is encouraging as the poor customers were more likely to use these remote shops. However the remote shops were less likely to have ACTs in stock.

- In Senegal low cost ACTs were made available to public and private sectors with a recommended price level by age band; the findings were that the recommended price level was respected in all sectors.

- In Kenya, artemether-lumefantrine (AL), an ACT, was distributed free of charge to RDT positive patients in a pilot study involving 9 community shops that operated using a franchising model (CFW shops). The preliminary results of the evaluation survey indicate that 9% of those getting AL obtained the drug through CFW shops. This data should be considered in the context of the scale up of free distribution of AL in government health facilities in the same period, with 86% of those getting AL from government facilities. Overall, access to AL rose from 15% to 41% of those buying an antimalarial.

- A review of whether interventions to improve quality in the private for profit sector were benefitting the poor found there is very little evidence on this – it is simply not studied in many evaluations. The review concluded that "many interventions have worked successfully in poor communities and positive equity impacts can be inferred from interventions that work with types of providers predominantly used by poor people."

- Training of private providers has been shown to improve quality. Following training of drug retailers in rural Kenya, the proportion of those buying anti-malarials who bought an adequate dose increased from 8% to 33%.

A number of conclusions and implications for AMFm follow from these findings, including:

There is substantial use of anti-malarials across the SES groups, although use by the poor tends to be lower than by the better off. If ACTs can be made available at a comparable price or for free, with education about the benefits, then it is likely that uptake of ACTs will increase and replace ineffective anti-malarials. This will benefit people from all SES groups, although a smaller proportion of the poorest. This is consistent with experience in other areas of health.

Many anti-malarials are purchased from private sector sources including private clinics and retailers, as well as from public sector providers. This is true for the poor as well as the better off, and reflects the reality that there are more access points for drugs in the private sector than public health facilities, in most countries and many settings. Hence by making drugs available through public, private and NGO channels, the AMFm should reach at least some of the poor.

Many countries want to scale up access to ACTs and tackle the relatively lower use of effective anti-malarials among the lower SES groups and for children. However, reaching groups who do not currently have access is hard and there is not clear evidence on how best to do so. Further work is needed to test and refine approaches, with research to see who among the population benefits, and how best to reach the poor and vulnerable.

The AMFm needs to be implemented in ways and alongside other interventions that will make it more likely to reach the poor and the poorest. These need to be designed at country level. For example:

- ACTs need to be made accessible through the types of outlets and services the poor use, in private and public sectors
- This will require training for the providers used by the poor, and in poor areas, as well as other measures to assure quality services, such as ensuring drug supplies; deployment of trained staff to poor areas; and supervision
- Messages and media for the IEC efforts need to be targeted to poor audiences
- Ensuring services that are already targeting the poor and vulnerable groups, such as NGO services for vulnerable groups, include ACTs for malaria treatment
- Using interventions to encourage prices to be set at levels that are affordable to the majority of the population
- Expanding free or low cost distribution arrangements targeted to reach those with least access to medicines.

The AMFm and efforts to reach the poor and poorest need to complemented by effective operational research and evaluation at country level. Countries can apply to the Global Fund (and others) for funding for operational research. It will require country level efforts to design appropriate research and monitoring, as well as central coordination to maximise learning from the findings.

1. Introduction

The purpose of this note is to summarise the evidence and issues around how the poor and the poorest groups in malaria endemic countries access malaria treatment, in order to consider how far the AMFm can be expected to reach the poor and ways to enhance its impact on the poor and the poorest groups. The note is intended as part of the briefing for AMFm and for discussion with interested partners. It was developed by members of the AMFm Task Force in February 2008 and updated in July 2008.

Defining the poor, the poorest and most vulnerable: for the purpose of this analysis, the poor are considered in absolute terms, as those living on less than $2 PPP per day (World Bank definition), which includes the majority of the population in most countries in Sub Saharan Africa. In relative poverty terms, the poor are defined in this paper as the lower three socio-economic status (SES) quintiles while the poorest are within the lowest SES quintile. Children under 5 and pregnant women are particularly vulnerable to malaria and there are potentially also specific vulnerable population groups at country level, based on conditions where they live, ethnicity etc.

2. What do we know about reaching the poor and vulnerable with malaria treatment?

Do the poor suffer from malaria?

The impact of malaria is concentrated in low income countries, to a greater extent than other diseases of public health importance. Gwatkin estimated that 58% of malaria deaths occur in the poorest 20% of the world's population[2]. Hence tackling malaria is a priority for the poor in absolute terms.

It is unclear whether the poorer groups within countries experience more malaria, while it is known that they face worse consequences in terms of mortality and severe illness[3].

What proportion of people have access to malaria treatment in poor countries?

Coverage with modern treatment is very variable across countries. For example, surveys suggest that 58% of children under 5 with fever receive antimalarials in Cameroon (2006), Zambia (2006) and Tanzania (2004/5), compared to 24% in Malawi (2006) and 34% in Nigeria (2003)[4]. The Malaria in Children report gives an overall estimate that some 34% of children with fever in Sub-Saharan Africa receive treatment with antimalarials. 23% of the children receive prompt treatment within 24 hours[5].

How unequal is access to anti-malarials?

As with other health interventions, the higher SES groups tend to have better access to treatment for malaria. Lack of access among the poorest appears greater in West & Central Africa (WCA) – analysis of DHS studies found that over 70% of lowest 2 quintiles lack access to treatment in WCA, versus around 45% in S&E Africa[6].

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[2] Gwatkin DR & Guillot M, 2000. *The Burden of Disease among the Global Poor: Current Situation, Future Trends and Implications for Strategy*. Global Forum for Health Research, Geneva.
[3] Barat et al, 2004. *Do Malaria Control Interventions reach the poor? A view through the equity lens*, Am. J. Trop. Med. Hyg, 71 (2s), pp174-178.
[4] Data from DHS, MIS and MICS compiled at http://www.childinfo.org/areas/malaria/maldata.php?cat=1&subcat=1
[5] UNICEF & RBM, 2007, Malaria & Children: progress in intervention coverage, UNICEF
[6] Barat, 2004 Figure 2 presents analysis of DHS data by Filmer, 2002, World Bank.

However, a study in Southern Tanzania suggests that within districts there is quite limited variation in uptake of treatment across SES groups[7], particularly across the lower two thirds of the population (whom we have defined as the relative poor).

Table 1 – Fever treatment in three rural districts in Tanzania (all age groups, 2001 survey)

	Poorest third	Middle third	Better off third	*Ratio T1:T3*
Any treatment	83%	80%	91%	*91%*
Any anti-malarial	31%	34%	46%	*67%*
Effective anti-malarial	11%	12%	24%	*46%*
Adequate dose of effective anti-malarial	8%	6%	19%	*42%*

Source: Njau, 2006.

Table 1 above also shows differences in treatment quality, with the better off more likely to receive effective drugs and adequate doses, reflecting higher spending and greater use of NGO services. This is confirmed in other studies in Tanzania e.g. Schellenberg et al found the highest SES quintile are twice as likely to receive appropriate treatment compared to the least well off quintile[8].

Data from a recent study in Uganda found some districts show much more disparity in access than others – see table 2 below. This relates to treatment with anti-malarials of children under 5, so the rates found cannot be compared directly to the Tanzania figures above. It is not clear why there is this difference – why for example there is less than 6% difference in uptake between first and fourth quintiles in 4 districts but over 20% difference in Kamwenge.

Table 2 – Use of anti-malarials among children by socio economic status (SES), in selected districts in Uganda (% of children under 5 who received any anti-malarial within 48 hours of onset of fever)

District	SES quintiles within the district				
	Lowest (%)	Second (%)	Middle (%)	Fourth (%)	Highest (%)
Kamuli (n=275)	17.0	23.9	27.2	22.7	-
Pallisa (n=248)	24.3	-	26.7	29.4	-
Soroti (n=191)	23.7	-	23.2	23.4	-
Kamwenge (n=218)	32.8	-	31.5	54.4	55.6
Kabarole (n=161)	24.6	29.3	34.3	27.1	42.1
Mubende (n=158)	-	34.8	-	37.0	43.2

Source: MMV, MOH Uganda and PSI, Nov 2007. *Understanding malaria health seeking behaviour in selected districts in Uganda – Draft report*

As Pearson noted, there can often be greater inequality in preventive than treatment interventions[9]. For example, Table 3 shows figures for Zambia, indicating more equitable access to treatment than to insecticide treated nets or indoor residual spraying. Clearly the challenges are different in ensuring access to such different types of commodity/ services.

[7] Njau, JD et al, 2006. *Fever Treatment and household wealth: the challenge posed for rolling out combination therapy for malaria*. Tropical Medicine and International health, 11, 3, pp 299-313.
[8] Schellenberg JA et al, 2003. *Inequities among the very poor: Health care for children in rural southern Tanzania*. Lancet 361: 561-566.
[9] Pearson M et al, 2008. *AMFm – Economic Appraisal and Access by the Poor*, DFID Health Resource Centre, London

Table 3 – Use of anti-malarials for children, insecticide treated nets (ITN) and indoor spraying in Zambia by socio economic status (SES)

	SES index				
	Lowest	Second	Middle	Fourth	Highest
% of children under 5 with fever who took anti-malarial drugs	52.6	52.9	68.3	68.9	*
% of children under 5 with fever who took anti-malarial drugs same day or next day	32.3	32.2	48.3	44.4	*
% of children under 5 who slept under an ITN the night before the survey	18.8	18.5	21.1	28.9	29.9
% of households sprayed in the previous 12 months	8.6	10.0	32.5	27.0	30.2

Source: Zambia National Malaria Indicator Survey 2006, Zambia Ministry of Health
* - small numbers so no data shown.

How well do public, private and NGO providers reach the poor?

These studies also show where people from each SES group get treatment from, including public providers and different kinds of private sector sources. Table 3 and 4 give some results from Tanzania and Uganda studies to illustrate this. The Tanzania data suggest that there is relatively little difference among SES groups in the use of public providers, drug shops and general shops; the biggest difference is in the use of NGO providers which is more common among the highest SES group.

Table 3 – Fever treatment by source by SES, 3 districts in rural Tanzania
% taking up treatment (not just anti-malarials) for all age groups, 2001 data

Source of treatment	Poorest third %	Middle third %	Better off third %	Total %	No.
Any treatment	83	80	91	85	*509*
Visited Government facility	24	21	23	23%	*136*
Visited NGO facility	3	3	13	7%	*39*
Visited drug store	28	24	27	27%	*159*
Visited general shop	30	34	26	30%	*179*

Source: Njau 2006

Table 4: Source of antimalarials by SES among all children treated for fever in Kamuli District, Uganda

Source of antimalarials	Lowest (n=22) %	Second (n=59) %	Middle (n=44) %	Fourth (n=86) %
Government provider / facility	40.9	39.0	22.7	38.4
Private health facility /worker	31.8	28.8	15.9	22.1
Pharmacy	9.1	6.8	15.9	15.1
Drug shop	18.2	25.4	43.2	20.9
Shop	0.0	0.0	2.3	1.2
Community Medicine Distributor	0.0	0.0	0.0	2.3

Source: MMV et al, Nov 2007

Data for one district is shown here in Table 4 for reasons of space. The report covers 4 districts and finds variation in the pattern of use across districts, with a clear picture that the majority of treatment for children is sourced from the private sector in all 4 districts analysed, and in most SES groups. For adults, the data is not available by SES, but shows that the majority of anti-malarials are sourced from private sector providers, with 8 – 40% using drug shops and pharmacies across six districts, versus 24-39% using a Government health facility or worker as their source of anti-malarials. There is strong data from 2 states in Nigeria showing that for both children and adults, about 75% of fever treatment takes place in the private sector. There is little difference across SES groups, though there is some evidence that private sector use is higher in the better off quintile. Within the private sector, about 40% of treatment

seeking is from patent medicine dealers, but these are a more important source of care for the poorest, compared with private hospitals and pharmacies which are used more by the better off. Within the public sector, the poorest make better use of primary care facilities, while public hospital benefits are disproportionately captured by the better off[10].

Data from a study in South east Nigeria compared treatment patterns between rural and urban mothers for their children in cases of fever and confirms this picture[11]. While the study did not look at socio-economic status, the urban mothers were generally better educated and more were employed; hence may on average have had higher incomes. It showed that 80% of both groups initially either gave treatment at home using drugs bought from patent medicine dealers or left over drugs, or took the child to a patent medicine dealer. Village health workers had a minor role in rural areas (with 8% of first contacts). Where there was subsequent treatment sought, the source was a private clinic (49.8% of urban, 42.4% or rural mothers), health centre (7.3% urban vs 38.0% rural) or hospital (42.9% urban vs 19.6% rural). This initial use of patent medicine dealers highlights the importance of enabling them to have effective medicines.

These studies indicate that all the SES groups make significant use of drug shops and private practitioners. Hence enabling distribution through the private sector will reach at least some of the poor and even some of the poorest. Njau's article on Tanzania comments: "… one might have expected the poorer households to be less likely to use drug stores, but this study found use relatively constant across SES groups, indicating that distribution through these outlets would not reach the better off alone. ….. Based on the current use patterns, delivery through government facilities will reach only a quarter of care seekers."

This partly reflects the numbers of outlets available – Tanzania has more than twice as many private health providers, drug shops and pharmacies as public sector health facilities. This is not just an East African issue - Senegal has around 1000 drug stores and 650 pharmacies, alongside some 930 public sector health facilities. Overall there are estimated to be at least 75,000 private sector access points, compared to over 45,000 public sector in sub-Saharan Africa[12].

Studies show variation in sources of medicines between and within countries, e.g. drug shops, stores, public and private providers. This presumably depends on the interplay of factors including regulations, financing policies, extent of dual practice by health workers, numbers of facilities as well as local factors such as trust in local providers, distribution of facilities, seasonal incomes etc. It demonstrates the importance of making ACTs accessible and affordable through diverse channels within a country in order to improve uptake.

Is there evidence on the impact of making ACTs available through the public sector health facilities?

Countries have been making a major effort to increase the availability of ACTs through the public sector. This scaling up of ACT use is however very recent and there is not data readily available on how far this is reaching the poor. A recent WHO

[10] Obinna Onwujekwe, 2008, unpublished data.

[11] Uzochukwu, B et al, 2008. *Rural Urban differences in maternal responses to childhood fever in South East Nigeria.* PLoS One 3(3): e1788

[12] Estimates of outlet numbers for selected countries by Dalberg consultants, based on fieldwork in 2007 and IOM reports.

report[13] shows substantial reductions in severe inpatient cases and deaths from malaria in four countries that have received funding for nationwide distribution of LLINs and provision of ACTs. The countries that showed greatest impact (over 50% decline in severe cases and deaths in a sample of facilities), Ethiopia and Rwanda, achieved mass distribution of LLINs, while less impact was shown in Ghana and Zambia where net supplies were inadequate or mass distribution came later. However, the report available at present does not show how far ACTs were available in practice, so it is not possible to assess how far the impact can be attributed to nets versus ACTs; this may come out from later analysis. It did not look at impact on the poor or poorest.

A study in one district in Zanzibar showed introduction of free ACTs in public facilities, with no stockouts, was followed by substantial reduction in malaria prevalence and admissions[14]. Subsequently LLINs were provided through mass distribution to cover 90% of children, and malaria prevalence fell further (10 fold reduction). During this period, child mortality declined by 52%, and much of this impressive decline is attributed to the uptake of ACTs. Use of the public sector increased as the medicines were known to be available and effective. The study did not look at how much the poor and poorest benefited.

In a survey done in Kenya, use of artemether-lumefantrine (AL) to treat uncomplicated malaria rose from 15% to 41% of those getting treatment for suspected malaria. The majority of this was delivered by the public sector which rose from 64% of AL provided in 2006 to 86% in 2008. This increase in AL use accompanied the scaling up of free distribution of AL in government health facilities.

The Uganda survey in 6 districts looked at uptake of ACTs which were in principle available for free from public providers at the time of the survey. Despite this, it found that use of ACTs was very low in all districts - about 10% of children received ACTs within 48 hours in the three Western districts, less than 4% in the three Eastern districts surveyed. Furthermore, many of these ACTs were sourced from the private sector. Thus free distribution of ACTs by the public sector is not sufficient to ensure uptake.

A reason for low uptake may be limited availability in practice, given the problems of stock outs that are especially common in rural areas. In the Tanzania pilot survey for example, 34% of the facilities in one district reported a stock out in the last three months. A survey in Zambia found that Coartem was unavailable in 42% of rural health units, 30% of urban health clinics and 25% of hospitals, while average stock out times for Coartem were 9.5 weeks for rural units, 6 weeks for clinics and 8 weeks for hospitals[15]. A study in Kenya showed there were various reasons why health workers were not prescribing ACTs although they were available in their facility. Concerns about future stock outs were a factor, alongside other issues[16].

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[13] WHO, 31 Jan 2008, *Impact of LLINs and ACTs measured using surveillance data in 4 African countries.* Prelim report.

[14] Bhatterai et al, Nov 2007, *Impact of ACT and ITN on Malaria Burden in Zanzibar*. PLOS, 11, e309

[15] MOH, Zambia 2007,

[16] Wasunna b et al, 2008. *Why Don't Health Workers prescribe ACTs? A qualitative study of factors affecting the prescription of AL*, Malaria Journal, 7:29. http://www.malariajournal.com/content/7/1/29

What about providing ACTs via community health workers as a way to reach the poor and the poorest?

There is increasing interest in providing home based care with access to ACTs through community health workers (CHWs) or other community based distributors – all are considered as CHWs in the discussion below.

There is a systematic review of the evidence on the impact of home based management of malaria, where treatment is provided by community members with training but no formal health qualification (i.e. CHWs)[17]. Only six studies provided credible evidence on health impact and the findings were mixed. Of the four that looked at the impact on mortality, one (in rural Ethiopia) showed a substantial reduction in child mortality, but the other three found no impact on mortality. One study showed a reduction in malaria incidence but not in mortality. Two studies looked at impact on transition to severe malaria and showed benefits. The studies were conducted in the 1980s and 1990s using CQ rather than ACTs.

There is early evidence of the acceptability of ACTs distributed by CHWs reported in a recent multi-centre study that covered four study sites[18]. Coverage of malaria episodes through CHW distribution ranged from 57% to 75%. However the study did not look at whether the poorest groups benefited.

There is little evidence on whether such mechanisms are effective in reaching the poor and the poorest. The only study found that assesses whether the poor were reached by this approach was an evaluation of the Home Based Management of Fever initiative[19] in Uganda. It indicated limited effectiveness – overall a 10% improvement in community effectiveness of malaria treatment[20]. It had most success in reaching the better off quintile (50% use), with levels of coverage across the poor – the lower four quintiles around 20-25%. "HOMAPAK use among the most poor was less than one half that in the least poor quintile (23% vs 50%)".

Hence further work is needed to learn from community based distribution approaches including how to expand and sustain a system on a large scale, how to make it cost effective and how to ensure it reaches the poorer households.

Is it essential to have free distribution of ACTs by CHWs?

In the four country study mentioned above, prices of ACTs varied by study site, ranging from free (Uganda) to 0.30 US$ (children aged 36-59 months in Nigeria). The coverage level achieved was not associated with the price of ACTs.

In Ghana, the policy of "treatment first, payment later" was adopted. Mothers accessed ACTs from CHWs at prices of 10 US cents and 20 US cents depending on the age of the child. They described the prices as cheap and affordable, and even those who could not pay on demand were optimistic that they could still treat their children and pay later. The provision of regular and readily available affordable pre-packs in the communities was convenient, saved time and increased productivity[21]. One mother commented "*It has reduced health care spending. When our children get*

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[17] Hopkins et al, 2007. *Impact of Home-based Management of Malaria on health outcomes in Africa: a systematic review of the evidence.* Malaria Journal, 6:134

[18] Ajayi et al, Jan 2008, *Feasibility and acceptability of artemisinin-based combination therapy for the home management of malaria in four African sites.* Malaria Journal **7**:6

[19] Nsungwa-Sabiti J et al, 2007. *Home-based management of fever and malaria treatment practices in Uganda.* Trans Royal Soc Trop Med & Hyg, 101, 1199-1207. The Home based management of fever initiative provided pre-packaged 3 day course of SP antimalarials called HOMAPAK (not ACTs), free of charge, for treatment of under 5 fevers.

[20] Effectiveness defined as treated within 24 hours of onset, with recommended anti-malarials in the right dosage.

[21] Browne et al, June 2007, Final report to TDR, study A41067

fever we rush them to the CHW to be treated. The price is good that is why parents are buying. The price is such that every parent can buy."[22]

In a study in Nigeria reasons for not seeking AL from CHWs were investigated. Among 284 caregivers not having sought treatment from CHWs, only 3 mentioned lack of affordability as the main cause.

This evidence suggests that free distribution is not essential especially if there is flexibility on timing of payment. But further work is needed to see whether the poorest are able to access treatment in these settings.

What about adding malaria treatment to existing services targeted to poor communities?

A recent study published by TDR reports on a three country trial to add several health interventions, including home based management of malaria, in communities that already have community directed ivermectin distribution for onchocerciasis control[23]. The community directed intervention (CDI) approach embodies the philosophy of primary health care in that communities are encouraged to take responsibility for organizing their own distribution of the drug ivermectin, The community took decisions on which additional interventions to adopt, how, when and where to manage them, and selected volunteers to implement the activities. Local health facilities were responsible for providing supplies and supervision. The study found that twice as many children with fever received appropriate anti-malarial treatment compared to control districts. However they found problems with sustaining drug supplies at community level – the health facilities were unable to maintain supplies consistently. The opportunity costs for volunteers increased sharply in several cases due to greater time commitments. As with many studies, there was no assessment of how successful the approach was at reaching poorer groups within the district.

Which ways of working with the private sector have been shown to benefit the poor?

A systematic literature review looked at this question in 2007[24]. Whilst there were almost 2,500 references identified, for only 5 interventions were there impact evaluations that looked at the distribution of benefits across SES groups; and in only 5 cases was there data to assess whether the intervention was in a poor community. The studies with data on distribution of benefits covered bed nets and franchising of health services; the findings were mixed, for example in urban Pakistan it was the better off who used franchised services, while in Bihar, India, there was no significant association between use of services and income, although clients with no education were more likely to use services than those with education. Some interventions were shown to be effective at improving quality (e.g. training non-pharmacy retailers in Kenya and Nigeria), but did not assess who was using the services.

The conclusion was "Few studies provided evidence on the impact of private sector interventions on quality and/or utilization of care by the poor. It was, however, evident that many interventions have worked successfully in poor communities and positive equity impacts can be inferred from interventions that work with types of providers

[22] Garshong, August 2008, Final report to TDR, study A41075
[23] TDR, 2008. Community Directed Interventions for major health problems in Africa: a multi-country study - Final Report. WHO
[24] Patouillard, E et al, 2007. Can working with the private-for-profit sector improve utilization of quality health services by the poor? A systematic review of the literature. Int J Equity Health 2007, 6.17 http://www.equityhealthj.com/content/pdf/1475-9276-6-17.pdf

predominantly used by poor people. Better evidence of the equity impact of interventions working with the private sector is needed for more robust conclusions to be drawn."

There is also a useful summary of approaches to working with the private sector in malaria control published by TDR[25].

What are the findings from the pilots to make ACTs available at low prices through private drug shops?

The Clinton Foundation is working with Government of Tanzania to pilot provision of subsidised ACTs in two districts. The subsidised drugs are made available through one private wholesaler to small, registered drug shops. The pilot was set up in October 2007 and there have been two monitoring surveys, one month and five months later, in these two districts and one control district; the results are still preliminary[26]. The surveys collect data from facility users and the shops themselves – these are not household surveys that look at who uses which services, but rather exit surveys which allow monitoring of who is buying which anti-malarials from the drug shops, and what the shops and public health facilities have in stock.

The findings of the review after five months included

- There was rapid uptake of ACTs: within one month 30% of consumers who purchased anti-malarials in the two intervention districts bought ACTs. After five months, this had increased to 44% of purchases. This compares to 1% of consumers buying ACTs before the pilot and 0.1% purchasing ACTs in the control district. Purchases intended for children were higher – 62% of the anti-malarials bought for children under 5 were subsidised ACTs.

- Uptake of ACTs also increased in the public sector in the two districts, so the availability of subsidised ACTs in shops does not seem to be displacing use of the public sector for malaria treatment (although this question cannot be answered definitively).

- Prices for ACTs were competitive with other anti-malarials. Where there was a suggested retail price (SRP), this resulted in lower prices for child doses and higher for adult doses than for the competing products (SP and Amodiaquine). ACT prices averaged $0.39 for infants in the district without an SRP and $0.25 with the SRP; for adults the prices were $0.50 without and $1.00 with the SRP. The SRP was closely followed, resulting in little price variation in that district while there was more price variation without the SRP.

- Prices in remote drug stores were not higher than in more densely populated areas, where there is more competition. This is encouraging for access by the poor, as the data showed that the shoppers in remote stores were more likely to be poor.

- Overall 60% of the drug stores held stocks of the ACTs when surveyed, (compared to 69% holding stocks of SP). However fewer of the drug shops in remote areas had subsidised ACTs in stock than those shops in busier areas with more competitors (38% vs 80%). This suggests further efforts may be needed to identify how to encourage distribution through such outlets in order to reach the poor living nearby.

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[25] TDR, 2006. *Partnerships for malaria control: Engaging the formal and informal private sectors*, WHO.
[26] Clinton Foundation, April 26 2008, *Tanzania Pilot ACT subsidy: Report on findings.*

- In one of the intervention districts there was substantial use by people from the lowest two quintiles (33% of customers surveyed, up from 18% found in the first survey). In the other two districts the poorest quintiles made up a smaller share of the customers (8%, 19%). Reasons for this are not clear, nor whether the poorer households are buying anti-malarials elsewhere, such as general stores. That would require further study using a household survey approach.

- There was no statistically significant correlation between socio-economic group and the choice of ACTs or the price paid. Thus poor customers were as likely to buy ACTs as the better off.

Further monitoring will be carried out with another report due in December 2008.

In Senegal there are similar findings of low prices being passed on where subsidised ACTs are being made available through public and private sectors[27]. A recommended price level was set and independent pricing studies showed that in public, faith based and private sectors, urban and rural areas, adherence was high to the recommended prices. There was however limited availability of the subsidised drugs in private pharmacies due to supply problems.

In Kenya, artemether-lumefantrine (AL) was distributed free of charge to RDT positive patients in a pilot study involving 9 community shops that operated using a franchising model (CFW shops). The preliminary results of the evaluation survey indicate that the contribution of CHW shops to overall access to AL was of 9%. However, these findings must be interpreted in the context of a massive scale up effort of AL availability in Government Health facilities (GHF) that coincided with the study. The overall proportion of patients treated with AL in the study area increased during the study period from 15% to 41%, and 86% of patients reported obtaining AL from GHF (up from 64% at baseline).

Other findings indicate a trend towards increased use of CFW shops by older children and adults than children under 5 years of age (10% vs 6% of all patients taking AL). Furthermore, treatment at CFW shops was more frequently based on weight (rather than on age) than at GHF, and the first dose was more frequently observed at CFW shops than at GHF. The study did not analyse access to CFW shops by SES quintile.

What are determinants of uptake of malaria treatment including ACTs?

On the **supply** side, the anti-malarials need to be available in local sources of treatment as well as affordable. Availability varies by country. In Tanzania for example, a study in four districts[28] showed a large number of general stores (675) stocked some drugs such as painkillers, with one third of these stores stocking antimalarials, usually Chloroquine. There were a smaller number of drug shops in these districts (43) virtually all of which stocked a range of anti-malarials, with diverse brands and active ingredients. The study concludes that "this active and highly accessible retail market provides opportunities for improving the coverage of effective anti-malarial treatment". On the other hand there are the problems of confusion over different brands, sale of ineffective products and monotherapies that bring risks of

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[27] Kone KG et al, Oct 2007. *Subsidized ACTs available for sale in private drug stores: experience in Senegal*, IRD, in Background paper 7 Summary of Field Research, AMFm Technical Proposal (or see Fig 16, AMFm Technical Design)

[28] C Goodman et al, 2004, *Retail supply of malaria related drugs in Tanzania*, Trop Med Int Health, Jun, 9 (6) 655-63.

resistance. A different study demonstrated that drug stores that are not meant to stock prescription-only drugs are in practice doing so[29].

There is scope for competitive markets for ACTs to develop in the private sector. Estimates of the supply chain in Uganda suggest that there are some 15 private sector importers, with about 50 private wholesalers. These operate alongside the centralised public medical stores and a joint procurement and wholesale agency for the NGO sector. Some 2,500 pharmacies and 8,000 general retailers sell drugs nationwide, for a population of some 25 million. Zambia has about 50 private wholesalers, and 40 retail pharmacies, as well as private clinics and drug stores mainly in urban areas. These wholesale markets are much larger than countries in West Africa such as Burkina Faso (with 5 wholesalers, for some 13 million population) and Cameroon (with 10 wholesalers for some 16 million population).[30]

On the demand side, the choice of treatment will only partly be based on the affordability of treatment from different sources. Non-price barriers such as distance may impede access to malaria treatment. For example, a recent trial in Ghana randomly allocated households to an intervention in which their National Health Insurance premium was paid for them[31]. Health service utilization was monitored for the next six months. Generally, utilization decreased with increasing distance from a health facility. Although households in the insured group living within 5 km of a health facility utilized primary care services more than the control households in the same vicinity, this was of borderline statistical significance. In contrast, households in the intervention group used non-formal source of care much less than control households. At distances 5 to 10 km away from the nearest health facility, the intervention households utilized primary care services significantly more than the control and although they tended to use non formal sources of care less, the difference between groups was not statistically significant. However, among those households living more than 10km away from a health facility there was no significant difference in the use of primary care services and non-formal sources of care between the intervention and control households.

Other factors will influence uptake of treatment from different types of providers. These include access to cash when it is needed; knowledge about and attitudes to different products; confidence in treatment and in advice from providers; willingness to change; and motivation. Changing the price of ACTs will only affect one of the factors in demand – the affordability – which can be expected to impact on uptake, but the demand will be affected by other factors too. Effective information, education and communication to the public and providers should help address the knowledge and attitude barriers. However the relative importance of different factors and how to alter these factors is not well understood.

What are the lessons from other efforts to target subsidies to the poor?

Looking at experience with cash and food subsidies intended to benefit the poor, the broad picture is that while most efforts to target support do favour the poor to some extent, some do not in practice. A major review by Coady, Grosh and Hoddinott[32] looked at 122 interventions intended to reduce poverty in 48 countries. They found that the median programme provided about 25% more resources to the poor than if there had been random allocations. However, the targeting does not always work –

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[29] C Goodman, 2007, *Drug shop regulation and malaria treatment in Tanzania – why do shops break the rules, and does it matter?*, Health Policy and Planning, 22, 393-403.

[30] Estimates of wholesaler and retailer numbers by Dalberg consultants based on fieldwork in 2007 and IOM reports.

[31] Ansah E, 2006. *The effect of reducing the direct cost of care on health service utilization and health outcomes in Ghana: A randomized controlled trial.* PhD Thesis, University of London.

[32] Coady, D et al. *Targeting of Transfers in Developing Countries: Review of Lessons and Experience*, World Bank

25% of the interventions did not benefit the poor, and this applied across various approaches to targeting the poor.

A key message from the review is that it is the detailed design and implementation practice that makes a huge difference to the impact in terms of benefiting the poor. The same message comes from the major World Bank review on Reaching the Poor[33].

A similar picture comes from a review by Coady[34] that notes, for example, while targeted food ration systems in general had limited success in targeting (median 37% of benefit to the lower 30% of the population), in one state in India 49% of the benefits reached the poor. Targeted food subsidies were shown to be more successfully at targeting and more efficient than universal food subsidies. How the benefit is offered makes a difference. For example, if the benefit is intended to get milk to poor children, then offering a portion of milk daily in slum areas will be better targeted to the poor than offering a week's supply of dried milk from a central point (as the better off will send a servant to collect the weekly supply).

The analysis of targeting identifies the importance of looking not only at how well targeted the programmes are (whether there is 'leakage' to the non-poor), but also at exclusion or under-coverage – how many of the poor are not reached. A review of social funds notes "Many programs start on a small pilot scale with the intention of scaling up. This leaves most villages and households without access to benefits."[35]

There are different methods of targeting such as geographic targeting to poor regions, targeting by age group, assessing households by means testing or by the community, and self selection. Many interventions use a combination of geographic and other measures. The value of geographic targeting to specific regions or districts will depend on how far poverty is spatially concentrated, which varies by country. The reviews note the trade offs to be addressed – between political support for the programme and the narrowness of its coverage; between poverty reduction objectives and other objectives it may have; and at a practical level between the cost and complexity of targeting methods and the costs and efficiency of the programme.

How relevant is this for AMFm? The objectives of the AMFm are to improve uptake of ACTs across population groups in order to achieve the public health benefits, including to avoid emergence of resistance. Because the well off already have better access to ACTs, in practice the AMFm is seeking to ensure wider access for the poorer majority (the 60 – 80% who cannot currently afford ACTs) and the poorest. While there will be leakage to the better off quintile, this can in part be justified by the externality of averting resistance; and the amount of leakage can be limited if the well off can still buy branded premium products in pharmacies at higher prices.

In addition some of the drawbacks of universal food subsidies, such as their influence on local food markets, as well as the ease of diversion and waste with food, are much less relevant to ACTs.

The greater concern is how to avoid under-coverage. The lessons from the literature suggest the importance of careful design and implementation of roll out interventions in order to succeed in reaching the poor; and continuing monitoring and evaluation of

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[33] World Bank, 2005, *Reaching the Poor* reports.
[34] Coady,D, 2004. Designing *and Evaluating Social Safety Nets: Theory, Evidence and Policy Conclusion*s. International Food Policy Research Institute, Washington
[35] Van Domelen, J, 2007. *Reaching the Poor and Vulnerable: targeting Strategies for Social funds and other Community Driven Programs*. World Bank Social protection Discussion Paper 711.

impact to refine and improve performance. The case for geographic targeting of efforts to reach groups who lack access will depend on country context; but experience suggests this can be useful especially if combined with other targeting measures.

Scale is also critical to reach the poor – interventions need to be able to scaled up and sustained. The temptation is to start programmes in better off or more accessible areas where interventions are easier to manage and monitor; but on equity grounds it may be preferable to start in the worst off areas, especially if there is a risk that full scale up will not be achieved.

3. Conclusions

Many countries have substantial use of anti-malarials across the SES groups, and although the use by the poor (defined as the poorer 60% of the population) tends to be lower than by the better off 40%, there is substantial use among the poor and the poorest through existing channels. If ACTs can be made available at a comparable price (or for free), with education of users and providers about their benefits, then it seems very likely that uptake of ACTs will increase and replace ineffective antimalarials. This will benefit people across the SES groups, although a smaller proportion of the poorest.

It is widely recognised that many anti-malarials are purchased from private sector sources including private clinics and retailers, as well as from public sector providers. The mix of sources varies between countries and within countries, but all show a 'mixed economy' for malaria drugs in a way that is not the case for TB or AIDS treatment. The limited data available on the sources of treatment by SES indicates that this 'mixed economy' is true for the poor as well as the better off, and even for the poorest.

Hence by making drugs available through public, private and NGO channels at comparable prices to existing medicines, the AMFm should reach the poor, as they already use these channels. To be sure of reaching the poor, it will be critically important for ACT roll out plans to be designed at country level to ensure drugs will be distributed through sources of treatment used by the poor and poorest groups, usually including drug retailers and private providers as well as public providers and registered pharmacies.

Many countries want to tackle relatively low use of anti-malarials among the lower SES groups and for children. Reaching the groups who do not currently have access is hard and there is not clear evidence on how best to do so, especially at large scale. Further work is needed to test and refine approaches.

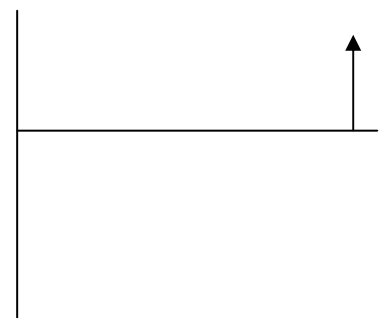
There still remain the problems with the quality of treatment – appropriate doses, duration and timeliness. These issues will require major efforts to complement increased availability of ACTs – particularly IEC and packaging. These are already being introduced in countries as part of ACT roll out, whether via the public sector, home based or private sectors. Positive results have also been shown from shopkeeper training (although not at large scale)[36]. Hence these are emphasised as essential supporting interventions alongside AMFm.

[36] Marsh VM et al 2004. *Improving malaria home treatment by training drug retailers in rural Kenya*. Trop Med Int Health 4 pp 451-460. Following training of drug retailers in rural Kenya, there was an increase in the proportion of those buying anti-malarials who bought an adequate dose from 8% to 33%.

The AMFm needs to be implemented in ways and alongside other interventions that will make it more likely to reach the poor and the poorest. These need to be planned and developed at country level to ensure that the messages are relevant to the poor and vulnerable groups in the country. This should include[37]:

- IEC / behaviour change to promote the advantages of ACTs, their availability at low prices, correct ACT use and prompt treatment of children
- Messages and media for the IEC efforts need to be targeted to poor audiences
- ACTs should be accessible through different channels including public and private, and make sure this includes the types of outlets and services the poor use
- Strengthening the quality of services in poor areas and those used by the poor, including provider training to cover the providers the poor use; assuring drug supplies; enhancing supervision[38]
- Building malaria treatment for the poor and vulnerable groups into services targeting those groups, such as service contracts with private or NGO providers; home based care; community based care
- Use interventions that encourage prices that are affordable to the majority of the population
- Expanding free or low cost distribution arrangements targeted to reach those least able to pay, with least access to medicines and most vulnerable to malaria.

The impact and cost effectiveness of these interventions are not proven and need to be demonstrated and improved at country level. Hence the AMFm must be complemented by effective operational research, monitoring and evaluation at country level, structured in ways that will enable an assessment of how well interventions are reaching the poor, the poorest and the most vulnerable groups. Operations research is planned as part of the AMFm, and counties can already apply to the Global Fund (and others) for funding for operational research. It will require substantial country level efforts to design appropriate research and monitoring, as well as central coordination to maximise learning from the findings.



[37] See also Pearson et al, 2008, op cit.

[38] Given the findings from various studies that facilities serving the poor are less likely to be well stocked with drugs and to be properly staffed. See references in Wagstaff et al, 2004, *Child health: Reaching the Poor*. AJPH May 2004, 94, 5