Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Affordable Medicines Facility – malaria (Phase 1) Monitoring & Evaluation Technical Framework

Version of 31 July 2009

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ABBREVIATIONS & ACRONYMS

ACT	Artemisinin-based combination therapy
AIDS	Acquired immunodeficiency syndrome
AMFm	Affordable Medicines Facility – malaria
AMT	Artemisinin monotherapy
API	Active pharmaceutical ingredient
AQ	Amodiaquine
CCM	Country Coordination Mechanism
CQ	Chloroquine
CTP	Competitive tendering process
DFID	Department for International Development
DHS	Demographic and Health Survey
DQA	Data Quality Audits
EAG	Expert Advisory Group
HAI	Health Action International Global Network
IEC	Information, education and communication
LFA	Local Fund Agent
M&E	Monitoring and evaluation
MERG	Roll Back Malaria Monitoring and Evaluation Reference Group
MMV	Medicines for Malaria Venture
MICS	Multiple Indicator Cluster Survey
MIS	Malaria Indicator Survey
NGO	Non-governmental organization
OR	Operational research
OSDV	On-site data verification
PR	Principal Recipient
RBM	Roll Back Malaria Partnership
RDT	Rapid diagnostic test
RFP	Request for proposals
SES	Socio-economic status
SIV	Supporting interventions
SP	Sulfadoxine-pyrimethamine
TA	Technical assistance
TDR	Special Programme for Research and Training in Tropical Diseases
TERG	Technical Evaluation Reference Group
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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OVERVIEW OF THE M&E TECHNICAL FRAMEWORK

1. Introduction

The Monitoring and Evaluation (M&E) Technical Framework sets out the approach to monitoring, operational research and independent evaluation of Phase 1 of the Affordable Medicines Facility Malaria (AMFm). It defines outputs and outcomes sought for the AMFm, which consists of two main components: (i) price reductions through manufacturer negotiations and buyer co-payments; and (ii) supporting interventions. Each component is a means to an end, which is the achievement of the stated goals of the AMFm.

The Technical Framework consists of nine sections. Following the Framework *Overview, Section 1* sets the scene with background information about traditional approaches to the financing of ACTs (i.e., the status quo), the AMFm approach and the purpose of the Technical Framework. *Section 2* explains what is measured. *Section 3* addresses how this will be done. In the next three chapters, core components of the Framework are individually examined: the monitoring of supporting interventions (*Section 4*), operational research (*Section 5*) and the independent evaluation (*Section 6*). Remaining chapters address "markers of clear failure (red flags) in the AMFm design", responsibilities and key events for the independent evaluation, and a timeline of those key events (*Sections 7-9* respectively).

It is envisaged that the Framework document will be used by a range of stakeholders. Principal amongst these are participating countries but also technical and development partners, contractors and the broader international health community. It may be of interest to policy makers whose malaria-endemic countries are not included in Phase 1 of AMFm but who stand to benefit from a potential global roll-out after Phase 1. Finally, the Global Fund Secretariat will also find it a useful reference.

AMFm Phase 1 will be independently evaluated per Global Fund Board decisions of November 2008 and May 2009. The results of this evaluation will assist the Board's decision in 2011 to expand, modify or terminate AMFm as a line of business within the Global Fund (Global Fund). To this end, the Framework lists evaluation questions and details design, methods, indicators, "red flags" and the responsibilities of respective parties for the independent evaluation. Guidance on performance measures and issues of design and implementation are also covered for additional components of the Framework that either support or otherwise inform the evaluation of AMFm.

2. Objectives

Phase 1 of the AMFm includes monitoring, operational research and an independent evaluation, with the following objectives by component:

- **In-country monitoring of supporting interventions (SIVs):**[1] to keep track of implementation progress on supporting interventions, identify problems that require the attention of managers, and inform subsequent decisions and action.

[1] *As defined in The Report of the Affordable Medicines Facility – Malaria Ad Hoc Committee to the Board of the Global Fund to Fight AIDS, Tuberculosis & Malaria. Eighteenth Board Meeting, November 2008. Available at: http://www.theglobalfund.org/documents/board/18/GF-B18-07_ReportAMFmAdHocCommittee.pdf*

- **Operational research (OR):** to enable learning by doing and alleviate constraints on implementation via studies whose findings will be applicable to the local context. The emphasis is on applied knowledge, in a particular country context. Additionally, OR involving multiple countries will be undertaken to examine cross-cutting issues for AMFm. Countries are responsible for the conduct or commissioning of county specific operational research (OR). The Global Fund Secretariat will contract out multi-country OR studies to leading research and academic institutions, to be selected by competitive tender.[2]

- **Independent evaluation**: to determine whether, and to what extent, AMFm Phase 1 achieves its objectives. This is the principal deliverable to be considered by the Board in 2011. Data analysis for the Independent Evaluation will be undertaken by an independent contractor to be selected by competitive tender. This contractor will not be responsible for in-country monitoring of supporting interventions and operational research but will have access to data from both sources.

3. Broad limitations of the M&E Technical Framework

The Technical Framework strives for an approach that is fit-for-purpose. It emphasizes relevance to the objectives of the AMFm Phase 1 and seeks a credible balance between methodological purity and pragmatism, which is necessitated by real-life constraints. These constraints include time (i.e., Phase 1 is very time-limited) and the need to promote country ownership of monitoring while respecting their explicit request to minimize additional M&E data collection, reporting requirements and work burden while they are busy implementing AMFm Phase 1. Phase 1 AMFm will contribute to the strengthening of local systems for monitoring, operational research and evaluation. However, the M&E work stream of AMFm Phase 1 is neither intended, nor designed, to solve all the deep-seated and long-standing weaknesses in systems for country monitoring, operational research and evaluation. The Technical Framework is constructed as a sensible balance of these multiple yet sometimes contradictory desires. Ultimately, it is important to recognize that this large scale complex intervention is being evaluated at national level in a range of diverse health systems. It is not a controlled experiment in a laboratory with passive subjects. This is an ambitious evaluation which presents scientific and measurement challenges. Components of the Framework address and manage this in different ways within the bounds of knowledge, available tools and what is feasible in terms of time and resources.

4. What is being measured?

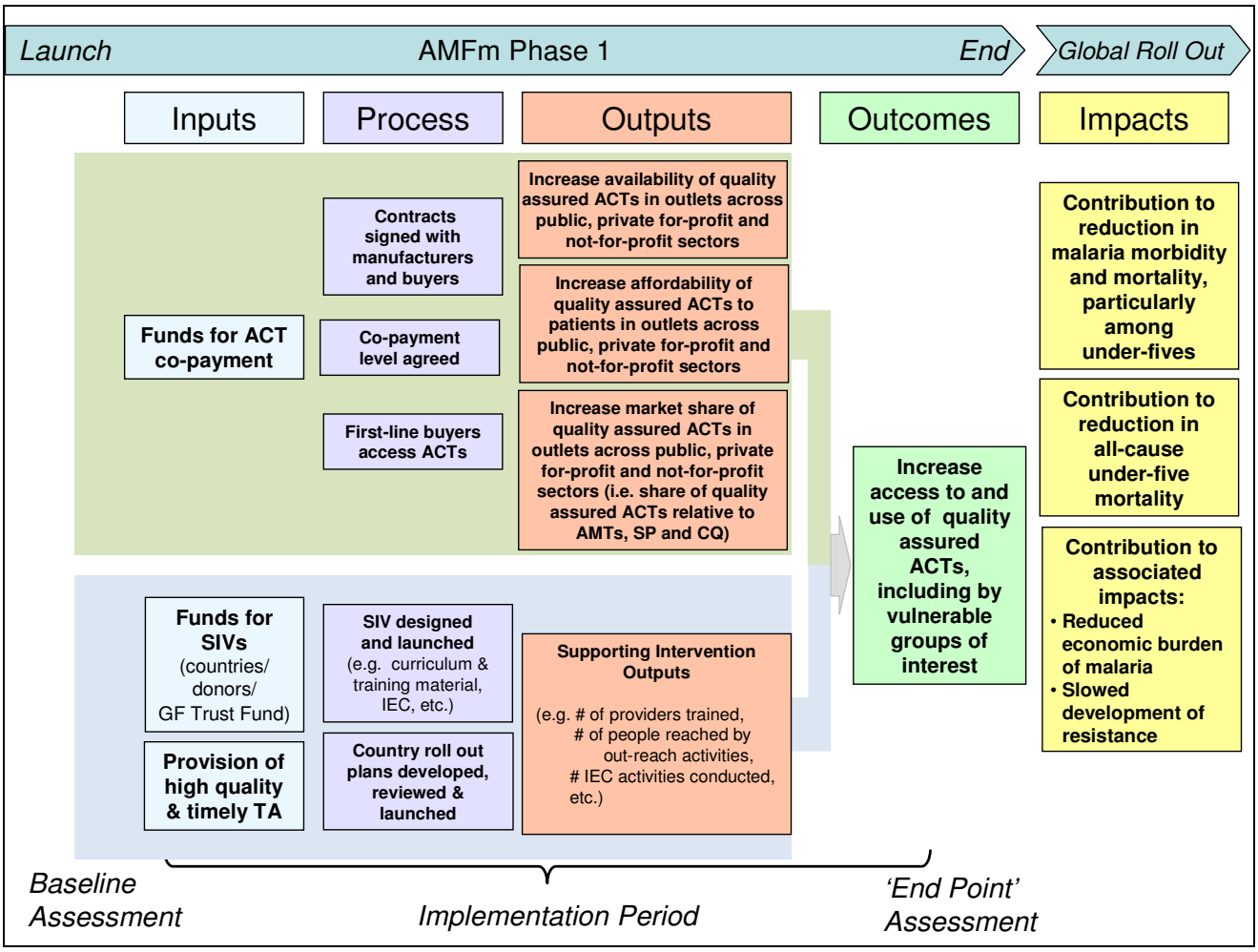
Figure 1 presents an overview of the *output* and *outcome* results sought for AMFm Phase 1. The Independent Evaluation will assess to what extent these outputs/outcomes are achieved. The evaluation will *not* be able to assess the long term impacts of AMFm Phase 1 due to the limited duration of the first phase. Country monitoring of AMFm supporting interventions via routine Global Fund grant performance practice will determine to what extent specified outputs are achieved for these activities.

While these two streams appear to be relatively independent at the input, process and output levels, they converge at the outcome and impact level. In other words, longer-term, population-based outcomes and impact of the AMFm will depend on interactions between ACT price reductions and supporting interventions.

[2] *Global Fund funded multi-country OR activity will be determined on the basis of consultation with partners who are planning a programme of AMFm related OR activity.*

Findings from both country-specific and multi-country operational research, as well as important contextual information, will feed into the independent evaluation.

Figure 1: AMFm Phase 1 Results Framework



5. Design

The Framework consists of the following components:

(5a) **Monitoring of supporting interventions**: Countries will design supporting interventions as part of their AMFm Phase 1 implementation plans. Indicators and targets for these activities are included in the Performance Framework of the country Global Fund grant related to AMFm. To assist countries and the comparability of information across countries, a list of established performance indicators will be provided by the Global Fund Secretariat, as part of the M&E Technical Framework, and countries can select from and/or build on these indicators. Indicators are agreed with countries during the grant amendment process, with reporting requirements similar to routine Global Fund country grant practice.

(5b) Operational research (OR): Two types of OR will be conducted under AMFm Phase 1.

- *Country-specific OR:* Countries will identify and either perform or commission operational research for their own use during Phase 1. The operational research questions should be directly relevant to the objectives of the AMFm and barriers to the achievement of these objectives. Therefore, specific operational research topics are expected to fall into one of the following broad categories:
  - (i) Constraints on the availability of co-paid artemisinin-based combination therapies (ACTs) through public, private for-profit and not-for-profit channels;
  - (ii) Factors that keep the retail prices of co-paid ACTs higher than those of chloroquine (CQ) and sulfadoxine-pyrimethamine (SP) (i.e., prices paid by patients across all sectors);
  - (iii) Factors that prevent a significant increase in the market share of ACTs relative to monotherapies (i.e., artemisinin-based monotherapies (AMTs), CQ, SP and amodiaquine (AQ)) across all sectors; and
  - (iv) Barriers to access and use of co-paid ACTs by vulnerable socio-economic groups of interest to the AMFm (e.g., the poor, children and rural residents), including issues of appropriate use of ACTs and compliance with the full course of treatment.

- *Multi-country OR*: This research will focus on cross-cutting topics spanning multiple AMFm countries. These topics will be identified by the Global Fund Secretariat, in consultation with technical partners in the Harmonization Working Group (HWG) of the Roll Back Malaria Partnership (RBM). The design, conduct and evaluation of these studies will be contracted out to expert academic and research institutes and will be subject to a competitive tendering process.

It is essential that these operational research studies are conducted; however, it is not crucial that they be financed by the Global Fund. The Global Fund Secretariat is consulting with the Clinton Foundation, the World Health Organization's Special Programme for Research and Training in Tropical Diseases (TDR) and others to explore coordinated options for parallel or joint financing for this work stream. An indicative timeline for this work is shown in Section 9 (Figure 5).

Coordination of research funding and activity will be central to ensuring that current key knowledge gaps are addressed. To this end, a roundtable meeting of relevant partners will be co-convened by the Global Fund Secretariat in September 2009 to specify research topics, consider research methods[3] and clarify responsibilities and funding. Whilst there will be a range of studies relevant to AMFm Phase 1, it is important to note that only a single independent evaluation report will be submitted to the Global Fund Board for its consideration.

[3] *Commissioners are likely to invite bidders to propose research design and methods as part of the bidding process on respective operational research studies.*

(5c) Independent Evaluation: The main assessment parameters of the independent evaluation are:

- **Availability** of quality assured ACTs in outlets[4] across the public, private[5] for-profit and private not for-profit sectors;
- **Affordability** of quality assured ACTs to patients in outlets across the public, private for-profit and not for-profit sectors (i.e., where anti-malarials are dispensed for a fee);
- **Use** of ACTs, including by vulnerable groups of interest (e.g., poor people, children, rural residents); and
- **Market share** ("crowding out") of quality assured ACTs relative to monotherapies and other undesirable anti-malarial treatments (e.g., AMTs, SP, CQ, AQ).[6]

In addition, the independent evaluation will: (a) examine ACT market dynamics (i.e., trends in, interactions among, and factors influencing demand, supply and price of ACTs) and; (b) appraise the structural, managerial and financial requirements for a potential global roll out of AMFm.

The Independent Evaluation at the country level will use a pre/post intervention design, with participating countries as the interventions sites and two or three non-participating countries, serving as comparators for the level of ACT availability, affordability, use and market share in countries where AMFm is not being implemented. The intervention under evaluation is the AMFm which consists of cheaper ACTs made possible by manufacturer negotiations and buyer co-payments, in conjunction to a raft of supporting interventions. Data for key parameters of the evaluation will be collected via baseline and end point surveys of: (a) outlets; and (b) households. The independent evaluation will draw upon evidence from different components of the M&E framework, with some activities undertaken by countries, and other activities undertaken by contracted parties.

Benchmarking: For all items related to service delivery and quality of care, the AMFm will be assessed against its objectives within the bounds of national treatment guidelines and World Health Organization (WHO) guidelines. For all counterfactuals, the benchmarks will be real-life counterfactuals (i.e, not hypothetical ideals), on the same scale, with multi-country diversity, and measured by the same indicators within the same period of implementation.

Key features of the Independent Evaluation are:

Baseline and End Point Surveys: As explained, a pre/post assessment of AMFm will be undertaken via surveys of outlets and households in AMFm participating countries and in two to three non-participating countries. It is proposed that these surveys be undertaken by up to three separate organizations already engaged in conducting ACT market surveys at the country level. Potentially these organizations are: ACTwatch, Medicines for Malaria Venture and Health Action International. The rationale and benefits to this approach are explained in the main sections of this M&E Technical Framework. Preliminary discussions are underway and proving to be positive in terms of possible interest.

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[4] *Outlets dispensing anti-malarials (free or for a fee) across all sectors (public, private for-profit and not for-profit) will be surveyed.*

[5] *The term private sector refers to both the formal and informal private, unless specified otherwise in this document.*

[6] *In the AMFm context, "crowding out" refers to displacing undesirable monotherapies with quality assured ACTs for the treatment of uncomplicated malaria. However, please note that the AMFm objective to "crowd out" CQ and SP is modified: (i) in areas where* P. vivax *transmission requires that CQ remain available for treatment purposes; and (ii) in areas of high transmission where SP is recommended for intermittent preventive treatment for pregnant women. The modification is done to take these policies into account.*

The responsibilities for data collection for baseline and end point surveys are different from the responsibilities for multi-country data analyses. These tasks will be done by different organizations. Indicators and datasets will be standardized across the three organizations to ensure the comparability of findings within the same country (over time) and across countries.

Conduct of Meta-Analyses of Country Data: An Independent Evaluator will be selected by the Global Fund Secretariat via a process of competitive tendering. It is envisaged that this contractor will be different from those organizations undertaking the baseline and end point surveys (i.e., Data Collection Contractors). This Independent Evaluator will have value-adding responsibilities for: standardizing data collection protocols in collaboration with and across all Data Collection Contractors; conducting the meta-analyses of country survey data;[7] providing an independent assessment of data quality; and identifying "red flags" (serious failures of AMFm design) if and where they occur. The Independent Evaluator will prepare and submit a report on evaluation findings to the AMFm Ad Hoc Committee.

The relationship between the Independent Evaluator and each Data Collection Contractor will include intellectual collaboration to ensure that the evaluation report has a foundation of high quality. Details of this relationship will be spelt out in separate contractual agreements between the Global Fund Secretariat and the Data Collection Contractors on the one hand, and between the Global Fund Secretariat and the Independent Evaluator on the other hand. Each of the agreements will specify, *inter alia*: deliverables; rights and obligations regarding access to data and data ownership; and the rights of each party to peer-reviewed publications that are based on data collected by the Data Collection Contractor. Datasets will be made available to the Independent Evaluator for purposes of transparency, quality assurance, standardization, validation, review of country-specific reports and the performance of cross-country analyses. All reports resulting therefrom will be submitted to the Global Fund and must acknowledge the source(s) of data and contributions from all parties. The Independent Evaluator shall not publish, disseminate or cause to be published or disseminated, the results of any such analyses in peer-reviewed journals prior to the datasets being made available in the public domain (i.e., via websites) of the Data Collection Contractor(s).

(5d) Comparators

Comparator (non-AMFm) countries: The merit of considering comparator countries is that it allows comparisons to be made between ACT availability, affordability, use and market share in countries where AMFm is, and is not, implemented. Consequently, this permits certain inferences to be made regarding observed changes and the possible "added value" of the AMFm. However, given the eligibility restrictions for countries participating in Phase 1, combined with the quasi-experimental design of the evaluation, conclusions drawn will be more limited than those based on a conventional experimental design, which compares "cases" and "controls." Nonetheless, the use of comparison countries increases appreciably the confidence with which observed changes may be attributed to the AMFm intervention, albeit with specific caveats.

[7] *Significant efforts will be made by the Independent Evaluator undertaking the multi-country data analysis, in conjunction with the contractors implementing the surveys, to ensure standardization of survey data collection methods, to render a meta-analysis feasible. The need for survey contractors to recognize the authority of the Independent Evaluator conducting the overarching analysis (who must also respect the provisions for data ownership and rights to publication by those who collected the data) is of paramount importance and will be explained during the negotiation and commissioning phase with each contractor.*

Alternative financing platforms: The Independent Evaluator will assess the extent to which AMFm Phase 1 meets its objectives. In addition, the Independent Evaluator will draw comparisons between the AMFm and alternative financing platforms that support access to antimalarials on a large scale in multiple countries. The comparison will use similar measures of (i) affordability, (ii) accessibility, (iii) market share, (iv) use and (v) cost-effectiveness.

The principal alternative financing platform to which the AMFm Phase 1 will be compared is the Global Fund's traditional (rounds-based, non-AMFm) approach to financing. The Independent Evaluator will compare the traditional approach and AMFm Phase 1, using similar measures of performance that are presented in Sections 6.3 and 6.4. Traditional grants approved by the Global Fund Board at about the same time as those under the AMFm could provide suitable comparators of performance during a *concurrent* time period.

The Independent Evaluator will also compare the historical trajectory of performance under traditional grants with the trajectory of performance under the AMFm. The Independent Evaluator will have access to the complete dataset from which the conclusions of the Five-Year Evaluation on ACT access were drawn, for the purpose of facilitating comparative analyses in a timely and transparent fashion.

Direct comparisons between performance under the traditional and AMFm financing platforms will provide opportunities to decide which approach (or combination of approaches) to financing better serves the twin objectives of expanding access to ACTs and displacing undesirable monotherapies from the market. The reports of all comparative analyses will be available in the public domain.

6. Markers of "clear failure (red flags) in the AMFm design"

Red flags (i.e., serious failings of AMFm design) have been identified. They are defined by core objectives of AMFm Phase 1 and measured by proposed indicators. Red flags are identified, justified and explained in the AMFm M&E Framework document.

In brief, three red flags are proposed:

(i) **Lack of ACT availability**
(ii) **ACT price violations**
(iii) **Failure to gain market share**

Other potential red flags are considered, and reasons for their non-adoption explained, with Section 7 providing cautionary notes regarding the interpretation of potential findings. Determining the occurrence of red flags is the responsibility of the Independent Evaluator. The Independent Evaluator will make recommendations to the AMFm Ad Hoc Committee about the interpretation of findings related to red flags. Recommendations will be based upon a combination of: findings from analyses; consultations with AMFm Phase 1 countries; and consultations with technical experts and key stakeholders as outlined in Section 8.2 of this Technical Framework.

7. Responsibilities & Major Events During the Independent Evaluation

The Global Fund Secretariat, as mandated by the Global Fund Board, is responsible for managing day-to-day operations of AMFm Phase 1, commissioning the Independent Evaluation of AMFm Phase 1, and managing related contracts. An independent Expert Advisory Group (EAG), chaired by Professor Barry Bloom (former Dean, Harvard School of Public Health), has been convened by the Global Fund Secretariat to provide technical advice to the Global Fund Secretariat on the design of the independent evaluation and draft reports from the independent evaluation. The rationale is to assure timely and high-quality advice from a body that is dedicated to the specific challenges of the AMFm, with a mix of skills that is customized for the specific purpose of the AMFm, and which has a finite lifespan. The EAG will have no role in the management or oversight of contractual processes for the independent evaluation, which will be the responsibility of the Global Fund Secretariat.

As mandated by the Global Fund Board, the AMFm Ad Hoc Committee has oversight of the implementation and independent evaluation of AMFm Phase 1. Based on findings generated by the Independent Evaluation, the AMFm Ad Hoc Committee will make recommendations to the Global Fund Board, at the end of Phase 1, on the future direction of AMFm within the Global Fund. As mandated by the Global Fund Board, the Technical Evaluation Reference Group (TERG) will provide "guidance with regard to the technical parameters of the design of the independent evaluation of the AMFm, under the oversight of the AMFm Ad Hoc Committee." The AMFm Ad Hoc Committee will consult with the Technical Evaluation Reference Group (TERG) accordingly. The Global Fund Secretariat will support the work of the AMFm Ad Hoc Committee and the TERG in relation to the Independent Evaluation of AMFm Phase 1.

At the country level, the Principal Recipient(s) has oversight responsibility for grant performance (including Global Fund grants for AMFm supporting interventions). The implementation of supporting interventions is subject to routine grant performance via standard Global Fund governance.

The Technical Framework concludes with a listing of key events for the independent evaluation, along with a timeline. **The timeline is based on Global Fund Board decisions in effect as of July 2009. The Global Fund Secretariat reserves the right to amend this timeline and other aspects of the AMFm Phase 1 M&E Technical Framework to comply with future decisions of the Global Fund Board, should the need arise. Such amendments may include but not be limited to: the scope or scale of the independent evaluation, the timing of end-point assessments, and the structure and contents of the evaluation framework.**

MONITORING & EVALUATION TECHNICAL FRAMEWORK

1. INTRODUCTION

This Technical Framework describes how monitoring and evaluation (M&E) will be conducted in Phase 1 of the Affordable Medicines Facility – malaria (AMFm). It sets out how results will be defined, what is monitored, what is evaluated, how it is to be done, and by whom. Results generated by the Independent Evaluation will be used by the Global Fund Board to determine whether there are "clear failures in the AMFm design,"[8] to inform their decision about the future direction of the AMFm (i.e., whether to globally roll out, modify or terminate AMFm).

Box 1: Characteristics of the M&E Technical Framework for AMFm Phase 1

- **Relevance to AMFm Objectives:** Components of the framework focus on data to assess the extent to which AMFm core objectives have been achieved.
- **Multi-sectoral Scope:** The M&E scope of work covers public, private for-profit and not-for-profit sectors.
- **Country Ownership:** Countries will lead the monitoring and in-country operational research aspects of the M&E work stream. They will have full access to all AMFm findings, from these and other areas, including the multi-country operational research and the independent evaluation.
- **Minimizing Data Collection Burden:** A mix of primary and secondary data sources are used to: reduce duplication; and to limit the incremental costs of the M&E exercise.
- **Sound Methods, Feasibility & Pragmatism:** These are important if Phase 1 timelines are to be met.

It is envisaged that this Framework document will be used by a range of stakeholders. Principal amongst these are participating countries but also technical and development partners, the Global Fund Board, Global Fund committees, the Global Fund Secretariat, contracted survey and analysis organizations, as well as the broader international health community. This may include other malaria endemic countries who may be interested in the AMFm, in the event that it is expanded and globally rolled out.

The AMFm is a new business line at the Global Fund. This chapter begins with a note on the achievements of the traditional business model or status quo approach to scaling up access to ACTs. This is followed by a summary of the main features of AMFm Phase 1. The remainder of this introduction provides an overview of the M&E Technical Framework. The reader is encouraged to revert to this introduction as a reference for subsequent discussions, particularly those examined in Chapters 3, 5 and 7. Three questions are of interest: (i) How well does the AMFm work on a large scale? (ii) How well does the AMFm work in comparison to traditional approaches to development assistance for access to ACTs? (iii) What is a wise approach to the appraisal and judgment of information yielded by the Independent Evaluation of AMFm Phase 1?

[8] *Annex 1 to Decision Point GF/B17/DP8: Principles for AMFm Policy Framework, Implementation and Business Plan.*

1.1 The effects of the traditional business line on access to ACTs

The recently completed Five-Year Evaluation of The Global Fund includes an assessment of the pre-AMFm approaches to development assistance for ACTs. The principal objective of Study Area 3 of the Five-Year Evaluation "was to comprehensively assess, in selected countries, the collective impact that the Global Fund and other national and international partners have achieved in reducing the disease burden of malaria."[9]

The findings noted below are particularly relevant to discussions in this Technical Framework.

Box 2. ACTs --- the current situation --- "perplexing and worrisome"

"The findings related to ACTs are the most perplexing and worrisome of the four primary malaria interventions because they show the least improvement. While there are data showing that most countries have purchased large amounts of ACT, there is little or no evidence of a corresponding increase in the use of ACT for treatment of children. A notable exception is Zambia, where 13% of children who were treated for fever were reported to have been treated with ACT in 2006. No other country showed coverage of ACT above 5%. This may be partly affected by bias in the mother's recall of specific drugs. The low levels of coverage of ACTs may also be because of the lag between financing disbursements, purchasing and distribution of drugs and the use of those drugs being reported correctly in surveys. If this is the case, new surveys should clearly show large increases in ACT coverage for 2008-2009. Another troubling issue with ACT has been the general lack of improvement in treatment (in most countries) by any measure. There is little evidence that more children receive antimalarial treatment for fever now than 5 or 7 years ago or that the services at the clinics have substantially improved."

Source: Final Report. Global Fund Five-Year Evaluation: Study Area 3. The Impact of Collective Efforts on the Reduction of the Disease Burden of AIDS, Tuberculosis and Malaria. Submitted to t*he Global Fund to Fight AIDS, Tuberculosis and Malaria by Macro International, Inc., in partnership with: African Population and Health Research Center, Harvard University School of Public Health, Johns Hopkins Bloomberg School of Public Health and the World Health Organization. March 2009. Page ES-38.*

The report of the flagship Global Fund Five-Year evaluation cited above provides evidence of the effects of a multilaterally financed and independently evaluated approach under the same institution that hosts and manages the AMFm as a new business line. It is instructive to note the following remark from the Five-Year Evaluation Report:

"Most importantly, five years is an extraordinarily limited amount of time over which to measure global level outcomes and impact, especially in a new program with a new model. Investments of both new resources and new approaches require time to take root and bear fruit."[10]

Another source describing and supporting reports of low ACT coverage for children in Africa is the RBM Partnership Executive Director's Report to the RBM Board on 14-15 May 2009 (RBM/EXD/2009/REP.1) which cites the most recently conducted national-level household surveys in sub-Saharan Africa. It states the following: "Nearly all countries in sub-Saharan Africa have shifted their national drug policies to include artemisinin-based combination therapies and substantially increasing financing and procurement for these medicines since around 2005…..While antimalaria treatment is moderately high across Africa, many children are still using less effective medicines

[9] *Source:* Technical Evaluation Reference Group Summary Paper. Synthesis Report of the Five-Year Evaluation of the Global Fund. *The Global Fund to Fight AIDS, Tuberculosis and Malaria. April 2009. Page 12.*

[10] Source: *The Five-Year Evaluation of the Global Fund to Fight AIDS, Tuberculosis and Malaria. Synthesis of Study Areas 1, 2 and 3.* March 2009.

and many countries have shown little or no progress in expanding coverage since 2000." The report includes Figure 8 from the UNICEF, RBM and Global Fund joint effort report released in April 2009 (entitled *Malaria & Children: Progress in intervention coverage*), which displays the household survey results and shows graphically the low coverage of ACT relative to other less effective medicines for children under five with fever.

Finally, recent market surveys by ACTwatch suggest that private sector prices of ACTs are still high for the poor, oral artemisinin monotherapies are still common on the market, and cheap but increasingly ineffective treatments such as chloroquine and sulfadoxine-pyrimethamine are still common.[11] The reader is encouraged to study these findings in detail.

1.2 AMFm Phase 1 & the Independent Evaluation

Rationale underpinning AMFm: Quick and effective treatment is essential to prevent disability or death from malaria. The lethal form of the malaria parasite, *Plasmodium falciparum*, is increasingly resistant to the older, inexpensive drugs for treating the disease. A class of highly effective drugs is available,[12] but there is a dual challenge in the treatment of malaria. *First,* the drugs (artemisinin-based combination treatments, or ACTs) are 10-40 times as expensive as the older failing drugs, such as chloroquine.[13] *Second,* since ACTs are the only first-line antimalarial drugs still effective against the most lethal forms of malaria, it would be disastrous from a public health perspective for artemisinin-resistant malaria to emerge and spread. Thus, the efficacy of artemisinin must be safeguarded.

Box 3: AMFm goals

- **Save more lives** by making ACTs more available and affordable
- **Slow down resistance** by reducing the use of artemisinin-based monotherapies, and increasing the use of ACTs

What is AMFm? The AMFm is an innovative financing mechanism to expand access to affordable artemisinin-based combination therapies (ACTs) for malaria, thereby *saving lives* and *reducing the use of inappropriate treatments*. The AMFm is a financing platform; it will enable countries to increase the provision of affordable ACTs through the public, private for-profit and not-for-profit sectors. By increasing access to ACTs and displacing artemisinin monotherapies from the market, the AMFm also seeks to delay resistance to the active pharmaceutical ingredient, artemisinin.

It is a 'buyer subsidy' for ACTs that operates via a 'co-payment'[14] at the top level of the procurement and supply chain to malaria endemic countries. The AMFm will facilitate increased use of ACTs by **reducing the cost of these drugs** in malaria-endemic countries and by ensuring that **additional activities** ("supporting interventions") are carried out to assist the **safe and effective implementation** of the AMFm. By increasing access to ACTs, the AMFm represents one component of a comprehensive response to the global problem of malaria.

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[11] *See: http://www.actwatch.info/home/home.asp*

[12] *ACTs are recommended by WHO for treating uncomplicated falciparum malaria. ACTs are not recommended for women in their first trimester of pregnancy.*

[13] *Kenneth J. Arrow, Claire B. Panosian, and Hellen Gelband, Editors. Committee on the Economics of Antimalarial Drugs Board on Global Health. Saving Lives Buying Time: Economics of Malaria Drugs in an Age of Resistance. 2004. Institute of Medicines of the National Academies. The National Academies Press, Washington. DC.*

[14] *The AMFm will pay a portion of the ACT price alongside payment paid by eligible first line buyers in malaria endemic countries. This ACT cost sharing arrangement between the AMFm and country first line buyers is termed a 'co-payment.'*

As a financing platform, the AMFm is neither a single-purpose service delivery project, nor a financing channel for a single model of service delivery, nor a platform that is limited to one sector, nor a substitute for country-led choices of what approach may be used for service delivery in a given context.

The AMFm is hosted by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), with key financial support provided by UNITAID, the United Kingdom, and potentially others, with technical support provided by members of the Roll Back Malaria Partnership (RBM). The technical design of the AMFm was developed with guidance from the RBM Partnership's AMFm Task Force, and is available at: *http://www.rollbackmalaria.org/partnership/tf/globalsubsidy/AMFmTechProposal.pdf* The AMFm has its origins in a 2004 report, "Saving Lives, Buying Time," produced by the Institute of Medicine, which called for a global subsidy of ACTs to reduce malaria mortality and delay resistance to artemisinin.[15,16]

AMFm Objectives:

(a) *Increase ACT availability*: The AMFm will contribute to making quality assured ACTs widely available through public, private for-profit and not-for-profit channels.

(b) *Increase ACT affordability*: The AMFm offers low cost quality assured ACTs to national wholesalers (called "first-line buyers") in public, private for-profit and not-for-profit sectors. Where first-line buyers sell ACTs, they commit to pass on the highest proportion of the price benefit from co-paid ACTs, as possible, to patients.

(c) *Increase use of ACTs:* This includes use in vulnerable populations of interest, such as poor people, rural residents and children under 5 years of age.

(d) *Increase the market share of ACTs ("crowd out" monotherapies)*: The AMFm seeks to increase the market share of quality assured ACTs relative to undesirable antimalarials, thereby displacing artemisinin monotherapies (which increase the likelihood of developing artemisinin-resistant strains of malaria parasites) and increasingly ineffective medicines for treatment, such as chloroquine. ACT resistance monitoring is beyond the *immediate scope* of the evaluation of AMFm Phase 1.

What is AMFm Phase 1? In November 2007, The Global Fund Board decided that the AMFm will be introduced in a phased manner in up to eleven countries. This first phase (Phase 1) will be assessed by a suitably qualified Independent Evaluator to be appointed via a competitive tendering process, to assess whether AMFm effectively meets its Phase 1 objectives. This is a process of independent evaluation.

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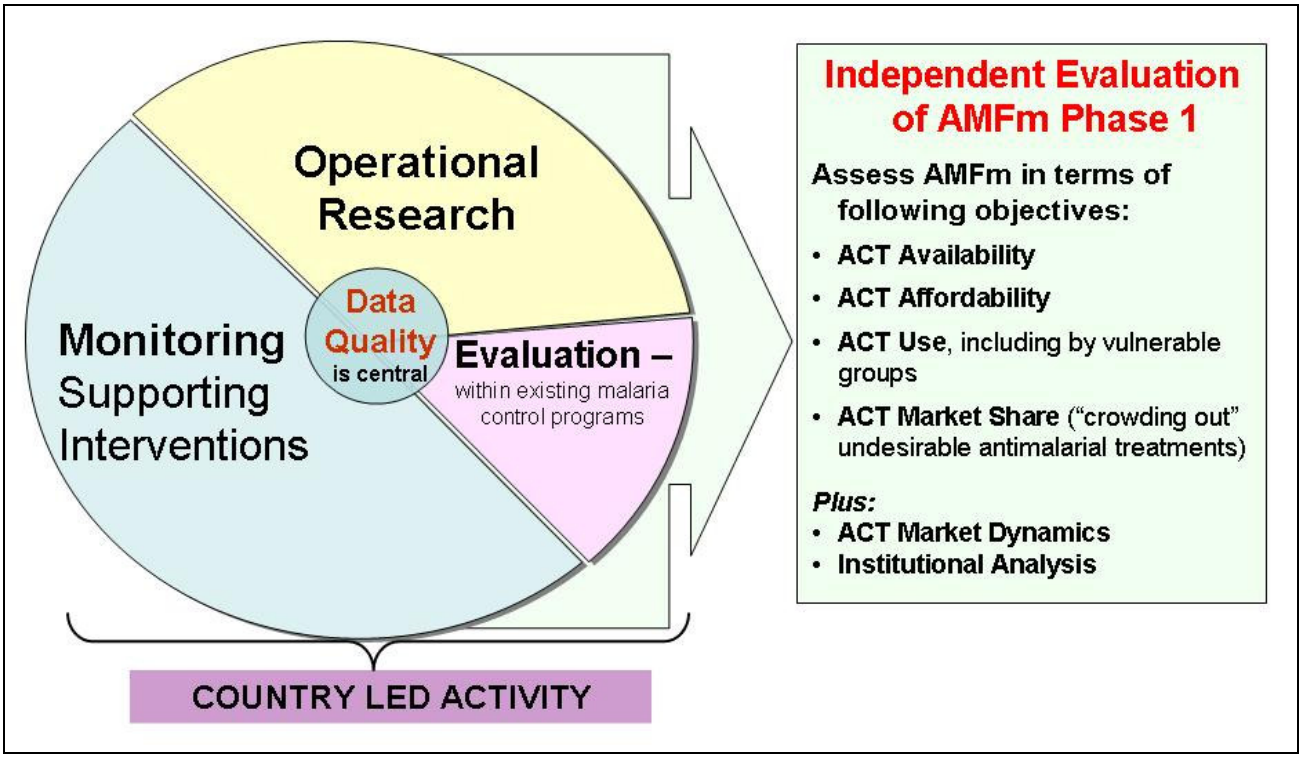
[15] *Kenneth J. Arrow, Claire B. Panosian, and Hellen Gelband, Editors. Committee on the Economics of Antimalarial Drugs Board on Global Health. Saving Lives Buying Time: Economics of Malaria Drugs in an Age of Resistance. 2004. Institute of Medicines of the National Academies. The National Academies Press, Washington. DC.*

[16] *More background information on the development of the AMFm is available at:* http://siteresources.worldbank.org/INTMALARIA/Resources/AMFmProcessEvaluation.pdf

1.3 Components of the M&E Technical Framework

Figure 2 shows components of the Framework. The nature and purpose of these components are briefly explained below.

Figure 2: Components of the AMFm M&E Technical Framework



1.3.1 Monitoring, operational research and evaluation within current malaria control programs

(a) Monitoring of supporting interventions and other contextual country-specific information: Countries have lead responsibility for monitoring the progress of supporting interventions and making necessary adjustments during program implementation. Many of these supporting interventions will build upon current National Malaria Program ACT-related activities. In addition, it should be noted that countries will be reporting on the status of implementation of all supporting interventions, whether financed by the Global Fund or other sources.[17]

Countries are also required to demonstrate active monitoring of registered private sector drug outlets (not in the informal sector). Such efforts build foundations for country systems to monitor the AMFm, i.e., in the event of a post-Phase 1 roll out. Chapter 6 provides suggestions for how this could be approached.

[17] *Countries will be requested to share reports prepared regarding supporting interventions funded by non-Global Fund sources so that this information is taken into account in the independent evaluation.*

Further, it will be important for countries to facilitate access to additional contextual information that may be relevant for the interpretation of findings during the Phase I time period, examples of which might include episodes of social or political unrest, or natural events like heavy rains that wash away dirt roads, thereby affecting ACT supply chains at the local level.

(b) Operational Research: Operational research (OR) is defined as: "*Any research that produces practical and usable knowledge which can improve program implementation in terms of effectiveness, efficiency, quality, access, scale, sustainability, regardless of the type of research (i.e. design, methods).*"[18]

Operational research is included in AMFm Phase 1 for pragmatic purposes: to generate knowledge that helps to resolve implementation problems, learn lessons, and test solutions related to AMFm implementation. In this way, OR will provide information that may also inform the global roll out of AMFm.

OR will be conducted at two levels in AMFm Phase 1:

- **Country-Specific OR:** This refers to studies whose findings will be applicable to the local context, to enable learning by doing and alleviate implementation constraints. Country-specific OR will be conducted by countries themselves or contracted out.
- **Multi-Country OR:** Multi-country OR will examine cross-cutting questions across subsets of Phase 1 countries.

(c) Evaluation within malaria control programs: Countries are expected to use the data generated by the AMFm independent evaluation to inform and build the knowledge base of their National Malaria Programs. However, countries are not directly responsible for undertaking the independent evaluation of AMFm; this will be contracted out to an Independent Evaluator.

Conversely, information generated by the evaluation of malaria control programs at country level, whether at a national or sub-national scale, through existing processes and plans regardless of funding source, will be made available to and used by the Independent Evaluator.

1.3.2 Independent Evaluation of AMFm Phase 1

All of the items described above (in 1.3.1) will feed into the independent evaluation of AMFm Phase 1, whose aim is to assess the extent to which AMFm Phase 1 meets its objectives of increasing availability, affordability, use and market share of quality assured ACTs, whilst reducing the availability and use of undesirable anti-malarial treatments.

[18] *A Joint Publication: The Global Fund to Fight AIDS, Tuberculosis and Malaria, USAID, World Health Organization (Special Program for Research and Training in Tropical Diseases), UNAIDS, The World Bank Global HIV/AIDS Program.* Framework for Operations and Implementation Research in Health and Disease Control Programs. *2008.* *http://www.theglobalfund.org/documents/me/FrameworkForOperationsResearch.pdf*

2. WHAT IS BEING MEASURED?

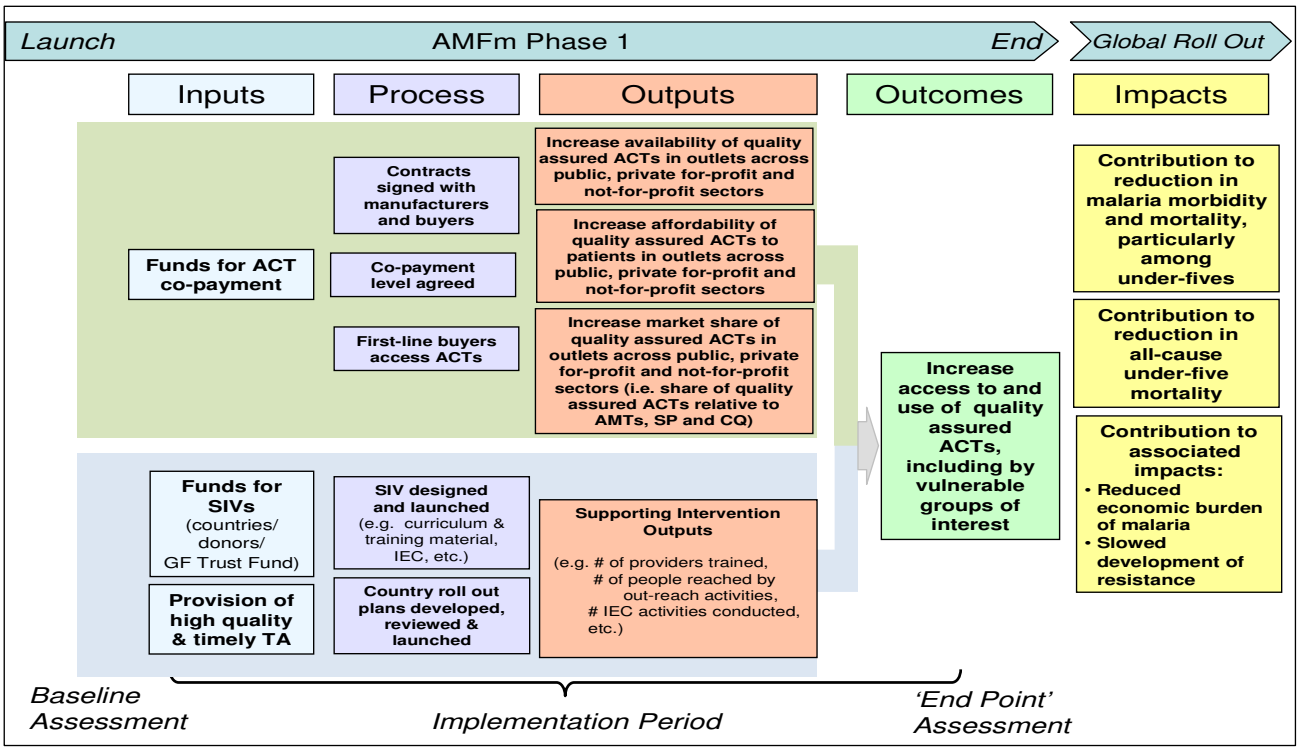
KEY MESSAGES:

- AMFm Phase 1 will be evaluated at the level of outputs and outcomes.
- Supporting intervention results will be monitored at the level of outputs.
- More detail is provided in other chapters of this document. Chapter 4 describes how the performance monitoring of supporting interventions will be done. Chapter 6 defines evaluation questions, indicators and methods upon which the parameters and metrics of the independent evaluation will be based.

2.1 Defining the Goal Posts

AMFm Phase 1 will *not* be assessed in terms of its impact on the broader goals of: reducing malaria related morbidity and mortality, and slowing down the development of resistance to ACTs. Given the short Phase 1 time period, results will be assessed in terms of output and outcome achievements that contribute to those goals. Figure 3 illustrates the underlying sequence of inputs, processes and outputs which are intended to lead to population-based changes in effective malaria treatment (outcomes) and subsequent reductions in malaria-related morbidity and mortality (impact). This sequence of activities and results provides a basis for AMFm Phase 1 monitoring and evaluation activities and is elaborated upon later in this report. Results for other components of the Framework (e.g., operational research) will be defined as their protocols are developed.

Figure 3: AMFm Phase 1 Results Framework (repeat of Figure 1 in Overview)



As seen in Figure 3, the stream of activities and results (price reductions) from manufacturer negotiations and buyer co-payments are closely paralleled by a stream of activities related to supporting interventions. While these two streams appear to be relatively independent at the input, process and output levels, they converge at the outcome and impact level. In other words, longer-term, population-based outcomes and impact of the AMFm will depend on interactions between ACT price reductions and supporting interventions.

3. HOW WILL MONITORING & EVALUTION BE DONE?

KEY MESSAGES:

Independent Evaluation

- The AMFm mechanism is the main "intervention" being evaluated at country level.
- The evaluation will use a pre/post intervention design with a comparison group of countries which will assess the ACT situation (access, price, use, market share) in intervention and non-invention settings. Surveys of outlets selling or distributing anti-malarial treatment (across sectors) combined with household surveys will be the methods used to obtain pre/post intervention data based on an agreed set of indicators. In addition to these core parameters, the independent evaluation will include analyses of: (i) ACT market dynamics; and (ii) institutional parameters in relation to the scalability of AMFm.

Monitoring

- Supporting interventions are at the center of country-led monitoring activities in AMFm.
- The design and methods of supporting interventions is chosen by countries – proposed in their AMFm Country Application – and reviewed for soundness by the Global Fund Technical Review Panel.

Operational research

- Operational research will use a mix of methods and be conducted by countries and/or contractors.

3.1 Design Overview

Table 1 summarizes design features and stakeholder responsibilities for different Framework activities.

Table 1: Design of Framework Components by Stakeholder Responsibility

Framework Component	Design Type	Implementation Responsibility
Survey Data Collection	• Pre/post intervention design	• Up to three contractors will be commissioned to conduct baseline and end point surveys
Independent Evaluation Analyses	• Comparisons made both within Phase I countries over time and between AMFm "intervention" and "non-intervention" (or "comparator") countries *In addition:* • *An analysis of ACT market dynamics* • *Institutional analysis in relation to the scalability of AMFm*	• An Independent Evaluator -- appointed via a Competitive Tendering Process (CTP) – conducts meta analyses of country data, taking into account monitoring reports, operational research findings and other contextual information
Supporting Interventions	• Designed by countries and approved for Global Fund funding support via Country Application process	• Phase 1 countries implement supporting interventions, including those funded by Global Fund and other funding sources
Operational Research	• *Country Specific OR*[1]: Designed by countries and approved for Global Fund funding support via Country Application process	• Phase 1 Countries
	• *Multi-country OR*: Themes approved by the Global Fund Secretariat. Designed by contractor(s) following a Request for Proposal process.	• Contractor(s) appointed via Competitive Tendering Process (CTP)

[1] Technical assistance is available to countries, where requested, to assist with the development of OR proposals.

3.2 Methods Overview

Different methods will be used to implement different components of the Framework. Table 2 presents a summary of methods by Framework component.

Table 2: Summary of Methods across M&E Framework Components

Framework Component	Proposed Methods	Comment
Survey Data Collection	• Primary data from surveys of outlets (all sectors)[1] and households - Use of "exit" interviews from outlets (all sectors)[2] - Use of mystery client visits to outlets, stakeholder interviews etc, as required	• Completed at baseline and end point of the AMFm implementation period by up to three commissioned contractors
Independent Evaluation Analyses	• Secondary survey data of outlets and households, i.e. for supplementary purposes or where primary data collection proves impossible for reasons of feasibility in terms of time and budget. Relevant data are: - ACTwatch, MMV and HAI survey data[3] - MIS, MICS, DHS[4] • Information from supporting interventions, operational research and other contextual information to be taken into account as well	• Completed by an Independent Evaluator appointed via CTP, with methods subject to review by technical experts
	ACT Market Dynamics Study • Methods to be designed by Global Fund selected contractor. To include: quantitative data analyses, modeling and qualitative studies, including in-depth interviews	• Methods subject to review by the Global Fund Secretariat, with technical experts in studies of market dynamics
	Institutional analysis in relation to the scalability of the AMFm • Methods to be designed by Global Fund selected contractor. To include: use of organizational appraisal techniques, interviews etc	• Methods subject to review by Global Fund Secretariat, in conjunction with technical experts in institutional analysis
Supporting Interventions	• Methods identified by countries, as part of the AMFm Country Application	• Methods to be reviewed by the Global Fund Technical Review Panel and Global Fund Secretariat
Operational Research	• *Country Specific OR:* Methods designed by countries	• Technical assistance will be available, if required. Methods to be reviewed by the Global Fund Secretariat
	• *Multi-country OR*: Methods designed by Global Fund appointed contractor(s)	• Methods subject to review by the Global Fund Secretariat, with technical experts

[1] Outlets are defined as any facility that dispenses antimalarials either free or for a fee.

[2] It is unlikely that it will be possible to include the informal private-for-profit sector using this approach because of its amorphous nature. The conduct of exit interviews will be subject to budget availability, data collection capacity and time; this will be discussed with the contractors conducting the survey.

[3] ACTwatch, Medicines for Malaria Venture (MMV) and Health Action International (HAI) already conduct ACT market surveys at country level. It is anticipated that the Global Fund Secretariat will contract these organizations and/or other suitable firms to conduct the baseline and end point surveys for the independent evaluation. See Table 11 for further details.

[4] MIS =Malaria Indicator Survey; MICS =Multiple Indicator Cluster Survey; DHS = Demographic and Health Survey.

Building on this, Sections 4-8 examine design and methodological detail by M&E component.

4. MONITORING OF SUPPORTING INTERVENTIONS

KEY MESSAGES:

- Countries are responsible for selecting supporting interventions and for monitoring their implementation.
- Established indicators for several supporting interventions are recommended for country use.
- Countries are required to monitor *registered* private sector outlets. This should be stepwise action to develop system capacity and readiness for a potential AMFm long term roll out. Such country action is **separate from and additional to the independent evaluation** undertaken by a contractor, who will assess the achievement of AMFm Phase 1 objectives, including ACT availability, price, use and "crowding out" of undesirable anti-malarial treatments, in public, private for-profit and not-for-profit sectors (formal and informal) (see Chapter 6).
- Data generated by monitoring efforts will be subject to routine Global Fund grant reporting and data quality checks.
- Stakeholder roles and responsibilities for the monitoring of supporting interventions are outlined.
- Countries will have the opportunity to exchange AMFm lessons and implementation experiences during an AMFm country workshop during the implementation phase.

4.1 Design & Methods of Supporting Interventions

In order to support the implementation of the co-payment for ACTs, countries are required to implement supporting interventions to improve malaria case management and ensure safe and effective scale-up of ACT use. Required supporting interventions include:

- Public awareness raising and education regarding ACTs;
- Training and supportive supervision for ACT providers;
- National drug monitoring (including pharmacovigilance, resistance monitoring and quality surveillance). In terms of drug quality monitoring, this will be done in accordance with standard Global Fund policy and practice for the quality assurance of pharmaceutical products.[19]
- Improving the regulatory environment for ACT distribution; *and*
- Efforts to reach poor people, children and other vulnerable groups.

Countries are also encouraged to include additional supporting interventions to improve malaria case management, such as introducing/expanding the use of diagnostics, and introducing patient-friendly packaging on co-paid ACTs.

[19] *For the purposes of AMFm Phase 1:(i)* Pharmacovigilance *will be monitored in accordance with recommended indicators (see Table 4). The scope and specific indicators will be further defined on the basis of a consultation that was hosted by WHO and MMV, and a forthcoming country consultation on July 10-11. (ii) Monitoring of* drug quality *must adhere to the requirements of the revised Global Fund Quality Asssurance Policy for Pharmaceutical Products, November 2009. Refer to Annex 1 - full text of the Revised Quality Assurance Policy, www.theglobalfund.org/en/procurement/policy/revision/ (iii)* Resistance monitoring *is vital and requires clinical and molecular studies for drug efficacy monitoring. This is beyond the scope of AMFm Phase 1 activity. The work of Technical Agencies, supported by other funders, in this area is of immense importance to the AMFm. The Global Fund Secretariat is exploring options for collaboration with the WorldWide Antimalarial Resistance Network.*

The funding and implementation of all supporting interventions that are financed by the Global Fund will be done in accordance with established practice for Global Fund country grants.[20] This means that proposed supporting interventions are described by countries, as part of their AMFm Country Application, and subject to the usual review process by the Global Fund Technical Review Panel, and then by the Global Fund Secretariat for programmatic technical soundness and feasibility and assurance of harmonization of reporting requirements.

4.2 Strengthening National M&E Systems

In addition to the monitoring of supporting interventions, countries are responsible for monitoring registered private sector outlets that sell ACTs. This is a new area of monitoring activity for many countries. Therefore, short-term expectations and requirements should be calibrated accordingly, in terms of what is feasible and practical. The learning nature of this endeavor is recognized by the Global Fund. Countries can apply to the Global Fund Secretariat as part of their AMFm country application for resources and support to undertake this work.

Key points are:

- **Why is this being requested?**
  If AMFm Phase 1 is globally rolled out in the future, country governments will be responsible for monitoring private sector activities, as they relate to AMFm. It is therefore important, within the *learning environment of AMFm Phase 1*, for countries to "road test" doing this, and for this experience to inform a potential AMFm global roll out.

Box 4: Monitoring of Private Sector by National Authorities
This limited monitoring of the private sector by national authorities is **additional** to that of the Independent Evaluation which will be undertaken by a contractor.

Monitoring of private sector activity (e.g. ACT availability and price) is new to many national authorities. It is prudent that the pilot environment of AMFm Phase 1 is used to test how national authorities will start to monitor the private sector in terms of AMFm and a global roll out.

Importantly, the Independent Evaluator will be responsible for comprehensively assessing the extent to which AMFm Phase 1 achieves objectives across public, private for-profit and not-for profit sectors (formal and informal), including reaching vulnerable groups. See Chapter 6.

- **What is expected?**
  Countries are expected to monitor a convenience sample of formal private sector drug outlets (*excluding* informal sector outlets).[21] In AMFm Phase 1, the monitoring and reporting requirements for this are modest. This is deliberate as it creates room and time for AMFm Phase 1 countries to plan and develop approaches to more comprehensive monitoring of the private-for-profit sector, in the event of a global roll out of AMFm.

[20] *This assumes countries will avail of the opportunity to apply to the Global Fund for at least partial funding of supporting interventions. Where countries do not apply for funding, they remain obliged to explain, in their AMFm Country Application, the nature of core supporting interventions being undertaken. Where funded from other sources, such interventions will be subject to the monitoring and evaluation requirements of the given funder. Countries will be requested to make these monitoring program reports of activities supported by other donors available to the independent evaluation contractor.*

[21] *However, private sector (including the informal private sector) activities related to AMFm objectives will be examined via the independent evaluation, which is separate and more comprehensive than country monitoring requirements.*

- **How will this be done?**
  Countries should use and build on current systems, information and practice. The convenience sample of private sector outlets can be drawn from sampling frames available for the independent evaluation. This sample could be stratified and include factors that may result in variation in ACT availability and price (e.g., urban/rural location or malaria transmission patterns). Other contextually known factors, such as variations in supply chain performance, should also be included. For example, it may be advisable to include outlets from areas where supply chain performance is known to be strong, as well as those areas where "stock outs" and disruptions are known to frequently occur. A limited number of process indicators are suggested below (Table 3).[22]

- **How often is this information required?**
  Countries are expected to submit monitoring reports of their performance against this indicator as part of their routine country monitoring reports to the Global Fund for the AMFm grant during AMFm Phase 1.

4.3 Indicators for Supporting Interventions & Strengthening National M&E Systems

Countries are responsible for monitoring the outputs of supporting intervention activities. Impact evaluation is not possible within the timeframe of AMFm Phase 1. Nevertheless, countries may opt to evaluate aspects of their supporting interventions package either by:

(a) Designing and implementing different approaches to implementing supporting interventions in different geographic areas, and/or target populations, and evaluating process, output and outcome progress with respect to program implementation; or

(b) Testing different methods or approaches to supporting interventions as part of their country portfolio of AMFm-related operations research.

Technical assistance is available for countries (if requested) to develop performance frameworks for the monitoring of supporting interventions. Performance Frameworks for Global Fund grants – including indicators and targets – are agreed during the grant amendment process. Table 3 recommends indicators to be used for some key supporting intervention activities. The following tool kit is recommended for identifying and selecting indicators: *Monitoring and Evaluation Toolkit: HIV, Tuberculosis and Malaria,* Third edition. 2009. See Section 4.4 regarding matters of data standardization for supporting interventions across countries.

Countries are not restricted to the recommended core supporting interventions and are likely to implement a range of other supporting interventions. Where countries propose additional supporting interventions which have no established indicators, countries should propose indicators which will be reviewed and agreed upon during Global Fund grant amendment discussions. Where indicators are established and "tried and tested," countries are encouraged to use them to assist comparability across countries; however, countries remain free to provide alternative or additional indicators, subject to Global Fund agreement during grant negotiation.

Ultimately, Principal Recipients (PRs) of Global Fund grants are responsible for ensuring the delivery of the performance framework for supporting interventions. Of course, it is at the discretion of individual Principal Recipients if they wish to delegate responsibility to qualified

[22] *The feasibility of regular monitoring of a purposive sample of outlets will be explored with countries. Although the samples will not be nationally representative, this approach will permit an assessment of trends over time among the purposively selected sample.*

parties for this process. For instance, a PR may choose to hire local firms to manage any additional monitoring requirements concerning the private sector which is currently beyond routine activity of National Programs for the Control of Malaria.

For activities to increase access among vulnerable socio-economic groups (e.g., lower socio-economic quintiles, children and rural residents), countries are encouraged to refer to local evidence and relevant publications, including a synthesis of options for reaching the poor undertaken by the RBM AMFm Task Force.[23]

For clarity, countries are expected to specify *by indicator:* data sources, numerator/denominator definitions, and any sub-group analyses to be undertaken for performance measurement.

Table 3: Recommended Indicators for Key Supporting Interventions

Note: *Indicators in this table refer to the intra-country monitoring of supporting interventions. They are NOT the same indicators as those proposed for the independent evaluation.*

Activity	Recommended Indicators	Collected How?	Collected When?	Responsibility
Public education and awareness campaigns	• Information, education, communication and behavior change actions (such as home visits or talks held on malaria) linked to specific interventions and their targets (number) *Source:* Indicator from M&E Toolkit • People reached by information, education and communication and behavior change communication community outreach or mass media (number and percentage) *Source:* Indicator from M&E Toolkit	Records of the National Malaria Control Program and surveys	In keeping with Global Fund grant reporting cycle	Principal Recipient
Provider training, monitoring and supervision to ensure patient safety	• Number of people trained for improved service delivery disaggregated by sector • Number of supervisory visits undertaken to ACT providers (by sector)	Administrative records	As above	As above
Pharmaco-vigilance[2]	• Number/proportion of pharmaco-vigilance reports within a specified period reporting adverse events attributed to ACTs • Number/proportion of complete reporting forms within a specified period[3]	To be specified by countries	As above	As above

[23] *For example: (1) AMFm Task Force Sub-Group on Reaching the Poor. Options for Reaching the Poor with Malaria Treatment. 2008. (2) World Bank. Davidson R., Wagstaff A., Yazbeck AS. (eds). Reaching the Poor with Health, Nutrition and Population Services: What Works, What Doesn't and Why. Washington DC. 2005. (3) World Bank. Yazbeck A. Attacking Inequality in the Health Sector: A Synthesis of Evidence and Tools. Washington DC. 2009. (4) Patouillard et al. "Can Working with the Private For-Profit-Sector Improve Utilization of Quality Health Services by the Poor? A Systematic Review of the Literature. International Journal for Equity in Health. 6:17. 2007.*

Activity	Recommended Indicators	Collected How?	Collected When?	Responsibility
Regulatory Preparedness	• What is the registration status of ACTs? • How many ACTs are registered? • What types of ACTs are registered? • How many importers/whole sellers are licensed? • Number of batch controls performed	Records from National Drug Regulation Authorities	As above	As above
Reaching the poor, children and other vulnerable groups	• To be specified by countries[1]	To be specified by countries	As above	As above
Strengthening National M&E Systems	• Number of visits[24] per quarter by National Drug Authority representatives to registered drug outlets [provide a breakdown of how this number maps to number of provinces/districts, and rural /urban areas visited]	To be specified by countries	As above	As above

[1] Indicators need to be developed based on the actual strategies adopted by countries to reach their poor and vulnerable groups. In relation to the selection of strategies (not indicators), there is no universally applicable and binding approach to reaching the poor with services [See: *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. September 2008. 18 pages]. Countries will be assisted with a menu of options to consider, not a prescription to follow. The following are examples of approaches that countries are encouraged to consider, with decisions depending upon local policies and operational realities selection, training, deployment and supervision of community health workers, mobile outreach services, social marketing approaches, free health services for pregnant women and young children.

[2] These indicators have been recommended following a joint WHO-Medicines for Malaria Venture technical conference in April 2009 [Reference: Pharmacovigilance Guidance for Countries Participating in AMFm Phase 1: WHO-MMV joint technical consultation on active pharmacovigilance monitoring with a special focus on AMFm. Geneva, April 2009]. As previously mentioned, to avoid overburdening Phase 1 countries, other indicators on PV would be *optional* to report to the AMFm during Phase 1. These are the minimum data required of countries. Countries are naturally very welcome to extend their monitoring of pharmacovigilance, and further indicators are suggested in the cited reference.

[3] 'Complete reporting forms' are defined as: (a) number/proportion of forms with identifiable patient, identifiable reporter, medicines reported as brand name and adverse event; (b) number/proportion of reports with recorded date of onset; (c) number/proportion of reports with recorded outcome of event.

4.4 Standardization of Supporting Interventions & Data Comparability Across AMFm Phase 1 Countries

In keeping with established Global Fund grant practice and the AMFm design, countries will design, implement and monitor a program of activities that support the nationwide scale-up of ACTs in their respective countries. Whilst the thematic nature of these supporting interventions is identical, the design and means by which countries implement the activities will differ. In keeping with sound development practice, country-specific approaches (instead of a command-and-control approach that requires uniformity everywhere) permit locally relevant choices and adaptation of lessons from elsewhere. This recognizes country diversity and is particularly important since

[24] *This topic was discussed with country officials at a consultation in Dar-es-Salam, 10-11 June 2009. Participants noted that this requirement is an essential minimum. It is a new activity in most countries; hence, short-term expectations must be modest.*

countries are at different "starting points," they are socially and culturally diverse, and the drivers of demand for health services vary within and across countries.

The AMFm evaluation would be easier if supporting interventions were standardized. But any quest for "standardization of supporting interventions" must be tempered by realism and a measure of humility. For example, nobody has any evidence of a single approach to reaching the poor that is guaranteed to work everywhere. In its report to the Global Fund Board in November 2008, the AMFm Ad Hoc Committee noted the following with regard to options for reaching the poor with ACTs: "There is much to learn about what works best where, and under what conditions... The RBM Task Force compiled information on promising options for reaching the poor and lessons learnt in their application… These ideas are not prescriptive…"[25] [For details, see: Report of the Affordable Medicines Facility-malaria Ad Hoc Committee. GF/B18/7.]

Evidently, it is not appropriate to impose a prototype package of supporting interventions on Phase 1 countries.

The challenge for the evaluation is the effect of this variation on the performance of actual AMFm mechanism (i.e. co-paid ACTs), and the interpretation of results across countries. Practical strategies to manage this situation are:

- The use of standard indicators for monitoring and reporting on supporting interventions (wherever possible) (see Table 3).

- Countries will be required to compile and report information on the specific nature, methods, pace and areas of supporting interventions under AMFm. In addition to relevant supporting intervention activity (including diagnostic activities) also being implemented via other country initiatives. This information will be submitted to the Global Fund Secretariat and made available to the contractor(s) undertaking the multi-country analysis. The process to finalize standard reporting requirements for this is underway and will be ready prior in advance of the signing of Global Fund grant amendments.

Ultimately, the contextual mapping and measurement (via monitoring activities) of supporting interventions is what is reasonable and practical to demand. In turn, this will enable explanatory (not causal) inferences to be drawn in terms of the performance – and performance differences – across countries, if and where they occur.

4.5 Quality of Data on Supporting Interventions

As part of their regular national M&E efforts, countries will be required to assure the quality of data on supporting interventions provided for progress monitoring purposes. These will be similar to measures applied to routine Global Fund grant management practice.

A description of the national data quality assurance (DQA) system will be provided to the Global Fund Secretariat by countries, upon grant signature. This is part of the roll out of the national M&E plan. The DQA system will define how the national authority will assure that high quality data standards are met. It is expected that countries will run and strengthen, as necessary, their national DQA system to ensure reported indicator data is of high quality. It is of paramount importance that countries define as early as possible how they plan to use the data generated by

[25] *For details, see Report of the Affordable Medicines Facility-malaria Ad Hoc Committee. GF/B18/7* http://www.theglobalfund.org/documents/board/18/GF-B18-07_ReportAMFmAdHocCommittee.pdf

the national M&E system, as data *use* by local authorities is a core link in the overall chain of data quality assurance. If appropriate, technical support can be requested by the countries to strengthen their existing national DQA system.

In addition, the Global Fund and its Partners will use routine data quality tools to assure that data presented by countries meets expected standards of quality:

- **Partners with Country Presence:** For example, WHO will follow-up the implementation of the AMFm Phase 1, including the roll out of the national M&E plan, and will alert the Global Fund Secretariat about data quality issues.

- **Local Fund Agent (LFA) On-site Data Verification (OSDV):** LFAs conduct an OSDV at least once a year per Global Fund grant. This process will also cover Global Fund grants that have an AMFm component (i.e., to cross-validate data quality reported by the PR). This process involves performing on-site data verifications at service delivery points and reviewing data, in a disaggregated form from primary data sources, against reported results contained in summary reports submitted to national authorities. Typically, one to three program indicators should be selected for an OSDV and verification exercise. Indicator data quality is rated according to a scale: A, B1, B2 or C. If required, the LFA will provide recommendations to remedy data quality issues.

- **Independent Data Quality Audits:** The Data Quality Audit tool and methodology was developed by the Global Fund and partners in order to:

  - Assess the ability of M&E systems to collect and report quality data

  - Verify the accuracy of reported data for key indicators at selected sites. The implementation of Data Quality Audits is independent from the routine grant management architecture of the Global Fund, and from the LFA. To guarantee independence, the implementation of the Data Quality Audits is outsourced to external service providers. A Data Quality Audit focuses on two to three indicators and 8 to12 service delivery points for each indicator. The outcome of each Data Quality Audit classifies a grant as having no, minor or major data quality issues, and potentially triggers M&E corrective actions at country level. The Global Fund Secretariat plans to run Data Quality Audits in almost half of the countries participating in the AMFm Phase 1 period (2009-2011).

4.6 Supporting Interventions & Stakeholder Roles and Responsibilities

Stakeholder roles and responsibilities for supporting interventions are described below (Table 4).

Table 4: Roles and Responsibilities: Supporting Interventions

Stakeholder	Key Roles & Responsibilities
AMFm Countries (a) **Principal Recipients** (PRs) (b) **Stakeholders** at the country level (public, private for-profit and not-for-profit)	Responsible for delivery / oversight of supporting interventions activity. PRs may delegate responsibility for implementation, and/or contract suitably qualified parties. Run a data quality assurance system. Responsible for implementing supporting interventions in line with the Country AMFm proposal.
Development Partners, including Technical Agencies, and the Private Sector	(i) Responsible for providing technical assistance, as appropriate; (ii) Identify key bottlenecks, solutions and share with Global Fund Secretariat; (iii) Identify bottlenecks specific to the private sector, or at the interface between the private and public sectors, and share solutions with the Global Fund Secretariat
Global Fund Secretariat	Oversee performance of Global Fund grants for supporting interventions and OR; including negotiating with countries, indicators, targets and the strengthening of the national M&E plan – once the grant has been approved by the TRP and Global Fund Board; oversee 'external' data quality efforts (OSDV and DQA)
Global Fund Technical Review Panel (TRP)	Review feasibility, technical soundness of design, methods and budget proposal for supporting interventions
Independent Evaluator	Contractor for meta-analysis to consider nature, scope and pace of supporting interventions, as potential explanatory factors when AMFm experiences at the country level are compared and contrasted
AMFm Ad Hoc Committee	Mandated by the Global Fund Board to provide oversight of AMFm Phase 1
Global Fund Board	To approve, based on TRP recommendation, country funding requests for supporting interventions, as part of AMF Country Applications

4.7 Disseminating Findings: Supporting Interventions

A country workshop during the AMFm Phase 1 implementation period provided countries with the opportunity to exchange lessons and experiences. This Technical Framework takes into account the discussions at the workshop.

5. OPERATIONAL RESEARCH

KEY MESSAGES:

- Country specific OR will be undertaken and /or commissioned and will be applicable to the local context. Additionally, OR involving multiple countries will be undertaken to examine cross-cutting issues for AMFm. The Global Fund Secretariat will contract out multi-country OR to leading research and academic institutions, to be selected by competitive tender.
- OR activity should be directly relevant to the objectives of the AMFm; broad categories are listed.

The purpose and structure of operational research opportunities in AMFm Phase 1 have been described earlier in this document. In brief, OR provides a vehicle via which countries can investigate, test and build evidence for effective program activities that are applied to their specific country contexts. It generates lessons and provides opportunities for "learning by doing." AMFm Phase 1 has two streams of OR activity which are explained below.

Importantly:

- It is essential that these operational research studies are conducted but it is not key that the Global Fund be the financier. The Global Fund Secretariat is consulting with the Clinton Foundation, WHO's Special Programme for Research and Training in Tropical Diseases (TDR) and others to explore coordinated options for parallel or joint financing for this work stream.

- Coordination of research funding and activity will be central to ensuring current key knowledge gaps are addressed. To this end, a roundtable meeting of relevant partners will be co-convened by the Global Fund Secretariat in September 2009 to specify research topics, consider research methods[26] and clarify responsibilities and funding. Whilst there will be a range of studies relevant to AMFm Phase 1, it is important to note that only a single report on the independent evaluation will be submitted to the Global Fund Board for its consideration.

- An indicative timeline for the conduct of operational research studies is shown in Section 9 (Figure 5). All activities must fit wholly or substantially within the duration of AMFm Phase 1.

5.1 Country-Specific Operational Research

Countries are encouraged to undertake country-specific OR as part of their M&E grant activities during Phase 1. This means identifying, and directly undertaking or commissioning operational research for their own use. Operational research questions should be directly relevant to the objectives of the AMFm and barriers to the achievement of these objectives. Therefore, specific operational research topics are expected to fall into one of the following broad categories:

- Constraints on the availability of co-paid ACTs through public, private for-profit and not-for-profit channels
- Factors that keep the retail prices of co-paid ACTs higher than those of CQ and SP (i.e., prices paid by patients in the private sector)
- Factors that prevent a significant increase in the market share of ACTs relative to monotherapies and other undesirable treatments (e.g., AMTs, CQ, SP, AQ)

[26] *Commissioners are likely to invite bidders to propose research design and methods as part of the bidding process on respective operational research studies.*

- Barriers to access and use of co-paid ACTs by vulnerable socio-economic groups of interest to the AMFm (e.g., poor people, children and rural residents), including issues of the appropriate use of ACTs and compliance with the full course of treatment.

Some country-led studies could include randomization of alternative approaches to expanding access to co-paid ACTs, thereby strengthening the experimental evidence generated by AMFm Phase 1. However, local determination of the focus of country specific OR is important, given proposals are assessed to be relevant, feasible, technically sound and affordable.

There are a number of relevant source documents that countries may find useful for the identification and development of country-specific OR proposals.

- RBM AMFm Task Force. Operational Research Priorities for the AMFm, October 2008

- WHO. Partnerships for Malaria Control: Engaging the Formal and Private Sectors. 2006. www.who.int/tdr

- A Joint Publication: The Global Fund to Fight AIDS, Tuberculosis and Malaria, USAID, World Health Organization (Special Program for Research and Training in Tropical Diseases), UNAIDS, The World Bank Global HIV/AIDS Program, Framework for Operations and Implementation Research in Health and Disease Control Programs. 2008. http://www.theglobalfund.org/documents/me/FrameworkForOperationsResearch.pdf

Countries are encouraged to develop OR proposals in line with the thematic areas listed above. However, other AMFm relevant ideas will be considered, where justified by countries (e.g. approaches to facilitate adherence to full treatment course regimes). When countries decide to undertake OR, the following is required:

- A brief description of concept and an estimated budget will be required as part of the AMFm country grant application

- The complete OR protocol (including methods) and budget will need to be shared with the Secretariat upon grant signature

OR methods are determined by countries and described in the OR protocol submitted to the Global Fund Secretariat. If required, technical assistance to design OR protocols is available. OR protocols are subject to scientific peer review and approval.

5.2 Multi-Country Operational Research

A major purpose of the multi-country OR is to address cross-cutting issues for the evaluation that are not readily studied or understood from the other forms of data collection and analysis. This could include addressing concerns about unintended effects of the AMFm, understanding reasons why things are or are not happening as expected, as well as how to improve its impact. The studies need to be selected to fill priority gaps and conducted in time for the findings to feed into the independent evaluation report and the Board decision.

Global Fund funded multi-centric OR activity will be determined on the basis of consultations with partners who are planning a program of AMFm-related OR activity. Subsequently, topics will be identified by the Global Fund Secretariat, in consultation with technical partners in the Harmonization Working Group (HWG) of the Roll Back Malaria (RBM) Partnership. The design, conduct and evaluation of such studies will be contracted out to expert academic and research institutes, and will be subject to a competitive tendering process. Countries (i.e. CCMs and/ or National Programs) will not have responsibility for undertaking multi-country studies. Potential OR themes are described in Box 5. Between two to five studies will be undertaken.

Box 5: Multi-Country Operational Research Themes

- How can the widespread over-treatment of malaria be effectively reduced, including through the subsidized distribution of rapid diagnostic tests?[27]
- How can the AMFm best contribute to increasing ACT access for those not currently receiving any treatment and what is the comparative impact and cost effectiveness of the private for-profit sector and free, community-based distribution?
- What is the most effective package of supporting interventions, including training and communications, to ensure the desired effects of subsidized ACTs in the private sector?
- How can the consistent supply of subsidized ACTs to private outlets in remote areas be ensured, including through the use of incentive schemes?
- A special study on pharmacovigilance: surveillance study to track ACTs adverse effects. To be useful, this must include baseline data on the scenario without the AMFm, otherwise it is impossible to begin to attribute to AMFm Phase 1 any observations from pharmacovigilance surveillance.
- What are the most effective approaches to achieve optimum ACT treatment adherence across different population and sub-population groups?
- What is the quality and efficacy of ACTs in the local supply chains (public, private for-profit and not-for-profit), including pharmaceutical content relative to packaging claims, and what are practical approaches to minimizing the supply and use of poor quality ACTs, i.e., beyond legislation alone?
- What is the uptake of ACTs by socio-economic quintiles, and what factors influence the uptake?

Note: These proposed themes will be validated and study topics selected by: (a) The Global Fund Secretariat, in consultation with country partners and other key stakeholders and; (b) the AMFm Ad Hoc Committee. A specific process for doing this has yet to be determined.

[27] *Today, some non-malaria fevers are being treated with ACTs, some with monotherapies. Supporting the scale-up of access to biological diagnosis of malaria and provider behavior in response to diagnostic outcomes is a key challenge facing many countries, particularly in a context of declining malaria transmission. Operations research around this issue is encouraged.*

6. INDEPENDENT EVALUATION

KEY MESSAGES:

- The independent evaluation will assess the extent to which AMFm Phase 1 achieves its objectives, namely to increase quality assured ACT availability, affordability, use and market share (versus undesirable anti-malarial treatments). It will assess the extent to which this is achieved across different sectors (public, private and non-profit), reaches rural/urban areas and vulnerable groups, such as poor people and children.
- The independent evaluation will be undertaken using a pre/post intervention study design where the intervention is the AMFm. Two to three comparison countries will be included to examine the pace and extent of ACT availability, affordability, use and market share, where AMFm is not being implemented.
- The "pre/post" intervention assessment will be conducted via surveys of (a) outlets dispensing/delivering anti-malarials across all sectors; and (b) households.
- This two point evaluation takes place over the course of twelve to fifteen months. Having said that, highly selective and "sentinel" monitoring of ACT prices and availability, undertaken by countries (Section 4) – separate and additional to the independent evaluation - will provide monitoring information between the formal pre/post survey points. These data will be supplemented by Global Fund centralized records of ACT volume and prices to first line buyers by country, and other forms of feedback from countries and partners, to provide some real time feedback of implementation in motion.
- Contractors who will conduct these surveys are already undertaking ACT market surveys at the country level. These contractors will be directly commissioned by the Global Fund Secretariat, whereas the Independent Evaluator undertaking the meta-analyses of survey data will be appointed via a competitive tendering process.
- The results framework, key evaluation questions, indicators and methods are presented.
- Studies on specific topics will also be conducted and used to inform the Independent Evaluation. Studies on: (a) ACT market dynamics; and (b) the "scalability" of AMFm will be conducted. The design and methods of these studies will be proposed by bidders as part of the competitive tendering process for the Independent Evaluation.

6.1 Conduct of the Independent Evaluation

The responsibilities for data collection for baseline and end-point surveys are different from the responsibilities for multi-country data analyses. Indicators and datasets will be standardized across the data collection contractors to ensure the comparability of findings within the same country (over time), and across countries.

The independent evaluation (i.e., data standardization, quality assurance, pre- post comparisons within countries, cross-country analyses and report preparation) will be undertaken by an Independent Evaluator, appointed via a competitive tendering process, whose approach best satisfies the technical and financial criteria specified in the Request for Proposals. The Independent Evaluator cannot be involved in any aspect of AMFm implementation. The Independent Evaluator will not be responsible for in-country monitoring of supporting interventions or operational research, but will have access to data produced from these sources.

Key requirements will include a demonstration by the successful applicant(s) of a strong and proven track record in (1) quantitative survey analysis of multivariate databases; (2) policy analysis of complex interventions (see below). More specifically, the Independent Evaluator must have world-class[28] expertise in the following areas:

(i) Design, conduct and supervision of service utilization and market surveys at the health facility, retail outlet and household levels in low-income countries;

[28] *"World-class" means among the best in the world in a given field, as indicated by verifiable markers of knowledge, practice and recognition by peers and independent bodies.*

(ii) Design and standardization of survey databases, and data quality assurance;

(iii) Qualitative research methods;

(iv) Analyses of data from multi-country surveys;

(v) Analyses of pharmaceutical market dynamics;

(vi) Epidemiology, health economics, public health, institutional development and reforms, anthropology, branding and marketing of innovative products and services, pharmacology, and the economics of drug resistance;

(vii) Convening and managing forums for multiple stakeholders to discuss research results and their implications for policy and practice; and

(viii) Writing reports based on findings from analyses, the research context and the global health architecture, and customizing presentations for different audiences.

There will be one comprehensive and final report of the evaluation of AMFm Phase 1 submitted to the Global Fund Board. This will be written by the Independent Evaluator, in accordance with terms and conditions specified in the Request for Proposals (also see Chapter 8). Whilst the main body of evidence used by the contractor(s) will be based on country survey data provided by a number of organizations already undertaking ACT market surveys (see below), key contextual and explanatory data will also be provided by countries, in terms of the nature and progress of supporting interventions and operational research. These data will be made available to the Independent Evaluator via the Global Fund Secretariat and the Global Fund Secretariat will put such data on a publicly accessible website. The contractor will also be required to undertake studies that examine features of global market dynamics and the "scalability" of the AMFm in the event of a global roll out.

In principle, the Independent Evaluator will have opportunities to recommend complementary and/or alternative approaches to the design outlined below, provided that the expected products remain essentially the same, the strategic framework remains the same, the recommended alternative is at least as clear and methodical as the one outlined here, with the conduct at least as transparent, with no material increases in costs to the Global Fund Secretariat, or significant increases in time required to undertake the exercise.

This Independent Evaluator will have value-adding responsibilities for: standardizing data collection protocols in collaboration with and across all Data Collection Contractors; conducting the meta-analyses of country survey data;[29] providing an independent assessment of data quality; and identifying "red flags" (serious failures of AMFm design) if and where they occur. The Independent Evaluator will prepare and submit a report on evaluation findings to the AMFm Ad Hoc Committee.

The relationship between the Independent Evaluator and the Data Collection Contractor will include intellectual collaboration to ensure that the evaluation report has a foundation of high quality. Details of this relationship will be spelt out in separate contractual agreements between the Global Fund Secretariat and the Data Collection Contractors on the one hand, and between the Global Fund Secretariat and the Independent Evaluator on the other hand. Each of the agreements will specify, *inter alia*: deliverables; rights and obligations regarding access to data and data ownership; and the rights of each party to peer-reviewed publications that are based on data collected by the Data Collection Contractor. Datasets will be made available to the Independent Evaluator for purposes of transparency, quality assurance, standardization, validation, review of

[29] *Significant efforts will be made by the contractor undertaking the multi-country data analysis, in conjunction with the contractors implementing the surveys, to ensure standardization of survey data collection methods, to render a meta-analysis feasible. The need for survey contractors to recognize the authority of the contractor conducting the overarching analysis is of paramount importance and will be explained during the negotiation and commissioning phase with each contractor.*

country-specific reports and the performance of cross-country analyses. All reports resulting therefrom will be submitted to the Global Fund and must acknowledge the source(s) of data and contributions from all parties. The Independent Evaluator shall not publish, disseminate or cause to be published or disseminated, the results of any such analyses in peer-reviewed journals prior to the datasets being made available in the public domain (i.e., websites) of the Data Collection Contractor(s).

6.2 Design of the Independent Evaluation

The Independent Evaluation is a prospective study using a pre/post test, quasi-experimental design that compares an "intervention group" of countries with a "non intervention" or "comparator group" of countries.

The design will enable assessment of changes and trends in the main outputs and outcomes related to the AMFm while seeking to minimize risks of conclusions that are not valid. This design is illustrated by Figure 4, where the upper row represents countries in which AMFm Phase 1 is implemented, and the lower row represents comparator countries. The AMFm consists of two components. One component is a price reduction through a combination of manufacturer negotiations and a "buyer subsidy" for ACTs that operates via a "co-payment"[30] at the top level of the procurement and supply chain to malaria endemic countries. The other component is a combination of activities called "supporting interventions" to assist the safe and effective implementation of the AMFm. The Global Fund Board authorized implementation of the AMFm Phase 1 as a package and it will be assessed as such.

Figure 4: Evaluation Design[31] with Comparison Group

Group of countries	Baseline	Intervention	Endpoint
Intervention Group:	O_1	AMFm	O_2

Comparator Group:	O_1	No AMFm	O_2

Applied to Phase 1 countries, this means:

- A **baseline** (or "pre-test") assessment will assess the availability, price and use of ACTs at country level before AMFm introduction. O_1 denotes the baseline assessment for the intervention and comparator groups.
- The **"intervention"** (i.e., the AMFm) is introduced and implemented in the intervention group but not in the comparator group.
- The **"end point"** (or "post test") assessment will assess the availability, price and use of ACTs at country level about 12-15 months after AMFm introduction. O_2 denotes the endpoint assessment for the intervention and comparator groups.

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[30] *The AMFm will pay a portion of the ACT price alongside payment paid by eligible first line buyers in malaria endemic countries. This ACT cost sharing arrangement between the AMFm and country first line buyers is termed a "co-payment."*

[31] *For further details about experimental and quasi-experimental design methods, see the following, amongst others:*

a. *Campbell, D., Stanley, J.* Experimental and Quasi-experimental Designs for Research. *1963.*
b. *Robson, C.* Real World Research: A Resource for Social Scientists and Practitioner-Researchers. *1993*
c. *Valadez, J, Bamberger, M. (eds).* Monitoring and Evaluating Social Programs in Developing Countries: A Handbook for Policymakers, Managers and Practitioners. *1994.*

Comparisons of the baseline and end point assessment will show if, and to what extent, change has occurred in levels of availability, affordability, market share and use of ACTs in countries.

The lower row (Figure 4) represents countries in which AMFm Phase 1 will not be implemented (i.e. 2-3 comparator or non-intervention countries). In these countries, surveys of ACT availability, price, use and market share will also be made, to assess the ACT situation where AMFm is not implemented. The dotted line between the rows indicates that the intervention and comparison groups do not have strict pre-intervention sampling equivalence.

Countries participating in AMFm Phase 1 were purposefully sampled (Table 5). Comparator countries will also be purposefully sampled using similar criteria, and the availability of secondary data. These countries have yet to be identified, and will be known in advance of survey baseline collection. To the extent possible, comparator countries will satisfy the same selection criteria as AMFm Phase 1 countries. Eligible Phase 1 countries that elect *not* to apply for AMFm Phase 1, or countries whose AMFm applications are not approved[32] by the Global Fund's Technical Review Panel, will be considered for selection as comparator countries. Clearly, these comparator countries are not matched "controls." However, whilst using some broad measures of malaria disease burden, coupled with some shared health system characteristics with AMFm Phase 1 countries, they will provide a useful means by which to observe the trajectory of ACT scale up compared to where AMFm is implemented. Readers are referred to the literature on quasi-experimental designs for more information on methods (see, for example, Campbell and Stanley, 1963; Robson, 1993; Valadez and Bamberger, 1994).

Table 5: Criteria Used for Purposeful Sampling of AMFm and Non-AMFm Comparator Countries

AMFm Phase 1 Countries Selection Criteria[1]	*Comparator Countries (non AMFm) Selection Criteria*
• High to moderate malaria mortality rates[2] • Previous country experience of large-scale ACT programs[3] • Status of private sector distribution levels • Strength of country monitoring and evaluation systems • Conducive regulatory environment, including ACTs as either "over the counter" medicines, or ACTs deployed at community level • Previous experience with ACT subsidy schemes to facilitate scale-up (principally at a sub-national level)	• High to moderate malaria mortality rates[2] • Previous experience of large-scale ACT programs[3] • Status of private sector distribution levels • Conducive regulatory environment, including ACTs as either "over the counter" medicines, or ACTs deployed at community level • Available ACT market survey data (i.e., available from organizations such as, ACTwatch or Health Action International Global Network (HAI) • AMFm Phase 1 eligible countries that do not participate in Phase 1 • Countries not directly bordering AMFm Phase 1 countries[4] (i.e., subject to feasibility and affordability)

[1] As defined in The Report of the Affordable Medicines Facility – Malaria Ad Hoc Committee to the Board of the Global Fund to Fight AIDS, Tuberculosis & Malaria. Eighteenth Board Meeting, November 2008. Available at: http://www.theglobalfund.org/documents/board/18/GF-B18-07_ReportAMFmAdHocCommittee.pdf

[2] A list of 25 countries was identified: Angola, Benin, Burundi, Comoros, Democratic Republic of Congo, Ethiopia, Gabon, Ghana, Guyana, Kenya, Liberia, Madagascar, Myanmar, Namibia, Niger, Nigeria, Rwanda, Sao Tomé and Principe, Senegal, Sudan, Suriname, Tanzania, Togo, Uganda, Zambia.

[3] Principally conducted at the sub-national level.

[4] In order to control for potential cross border "leakage" of AMFm co-paid ACTs.

[32] *It is important to note that even these are not matched controls because countries whose applications are not approved differ in some ways from those whose applications were approved. However, they are among the closest to a match because they were among those pre-screened and invited to submit applications.*

AMFm in areas of moderate to low malaria endemicity: AMFm Phase 1 is being tested in countries of high to moderate malaria mortality rates. In the event of global roll, it would be useful to know how the mechanism performs in areas of moderate to low malaria endemicity (i.e. more so as prevention measures are becoming increasingly successful). Whilst the country sample is not stratified by different levels of malaria mortality rates (i.e., high to moderate versus low to moderate), where malaria profiles differ *within countries* (e.g., Kenya), relevant sub-analysis will be undertaken.

6.3 Independent Evaluation Questions

Table 6 lists specific evaluation questions based on AMFm objectives.

Table 6: AMFm Objectives by Independent Evaluation Questions

AMFm Objective	Independent Evaluation Questions
1. Increase ACT Availability	Q 1.1 Has the AMFm mechanism helped increase the availability of quality assured ACTs to patients across public, private[2] for-profit and not-for-profit sectors, in rural/urban areas?
2. Increase ACT Affordability	Q 2.1 Has the cost of quality assured ACTs to patients been reduced at public, private for-profit and not-for-profit outlets in rural/urban areas to a price comparable to the price of most popular anti-malarials?
3. Increase ACT Use	Q 3.1 Has the AMFm mechanism helped increase use of quality assured ACTs, including among vulnerable groups, such as poor people, rural residents and children?
4. "Crowd out" AMTs, CQ, SP	Q 4.1 Has the AMFm mechanism helped increase the market share of quality assured ACTs relative to all anti-malarial treatments in the public, private for-profit and not-for-profit sectors in rural/urban areas?

Evaluation questions addressing other topics of special interest are listed in Table 7.

Table 7: Evaluation Questions for Market Impact Study & Institutional Analysis

Additional Study Topic	Evaluation Questions
5. ACT market dynamics	Q 5.1 What are the plausible effects of AMFm Phase 1 on ACT market dynamics (trends in, interactions among, and factors influencing demand, supply and price of ACTs) at the regional and global levels?
6. Institutional analysis (regarding the scalability of AMFm)	Q 6.1 This study will define functions, institutional and financial requirements for a potential global roll-out of AMFm, with emphasis on the following question: "What will it take to run a global phase of AMFm?" It will identify options for managerial and institutional systems and structures for a potential global roll out of AMFm.

6.4 Indicator Framework for the Independent Evaluation

Outlet and household surveys will use a select number of pre-agreed indicators to answer core evaluation questions (Table 8). These indicators are based on earlier work undertaken by the RBM Task Force on AMFm[33] and are subject to modification and further standardization on the basis of technical discussions with survey organizations and the Independent Evaluator conducting the multi-country data analysis. They may be modified to take account of the feasibility of data collection. Any subsequent modifications to individual indicators will not compromise the assessment of the evaluation questions. However, if it becomes clear that parts of the evaluation cannot be done because of severe capacity constraints at the country level, those parts of the evaluation will be scaled down to fit with realities. Such decisions will be made on a case by case basis and documented.

Table 8: AMFm Phase 1 Evaluation Questions & Indicators

Evaluation Questions	Indicators
Q 1.1 Has the AMFm mechanism helped increase the availability of quality assured ACTs[1] to patients across public, private[2] for-profit and not-for-profit sectors in rural /urban areas?	(1.1) Proportion of outlets in rural /urban areas that have any anti-malarials in stock at the time of survey visit (1.2) Proportion of outlets in rural /urban areas that have non-artemisinin monotherapy or non-artemisinin combination therapy in stock at the time of survey visit (1.3) Proportion of outlets in rural /urban areas that have artemisinin monotherapy in stock at the time of survey visit (1.4) Proportion of outlets in rural / urban areas that have non-quality assured ACTs in stock at the time of survey visit (1.5) Proportion of outlets in rural / urban areas that have quality assured ACTs in stock at the time of survey visit (1.6) Number and percentage of rural / urban outlets with no reported stock outs of nationally recommended anti-malarial drugs, lasting more than one week, at any time, during the last 1 month (1.7) Proportion of the rural /urban population living in areas that have access to a full course of an adult treatment with a quality assured ACT (1.8) Proportion of the rural / urban population living in areas that have access to a full course of a child treatment with a quality assured ACT
Q 2.1 Has the cost of quality assured ACTs to patients been reduced at public, private for-profit and not-for-profit outlets in rural/urban areas to a price comparable to the price of most popular anti-malarials?	(2.1) Median cost to patients[3], of a full course of treatment (adult/child) with quality assured ACTs, in rural /urban outlets (2.2) Median cost to patients[3], of a full course of treatment (adult/child) with non-quality assured ACTs, in rural /urban outlets (2.3) Median cost to patients[3] of a full course of treatment (adult/child) with artemisinin monotherapy, in rural / urban outlets (2.4) Median cost to patients [3] of a full course of treatment (adult/child) with other anti-malarials (CQ, SP) in rural / urban outlets (2.5) Cumulative percentage mark up between retail median price of a full treatment course with quality assured ACTs (adults) and wholesaler median price

[33] *Roll Back Malaria. AMFm Working Group. Monitoring & Evaluation and Operational Research. Affordable Medicines Facililty – malaria. Technical Proposal to Increase Access to Malaria Medicines. Background Paper 3. November 2007.*

Evaluation Questions	Indicators
Q 3.1 Has the AMFm mechanism helped increase use of ACTs,[4] including among vulnerable groups, such as poor people, rural residents and children?	(3.1) Proportion of children (by age band), with fever in the past 2 weeks who received ACT treatment by source of provider (3.2) Proportion of children (by age band), with fever in the past 2 weeks who received ACT treatment within 24 hours of fever onset by source of provider (3.3) Proportion of children (by age band), with fever in the past 2 weeks who received any antimalarial treatment by source of provider (3.4) Proportion of adults (>15 years) with fever in the past 2 weeks who received ACT, by source of provider (3.5) Proportion of adults (>15 years), with fever in the past 2 weeks who received ACT within 24 of fever onset by source of provider (3.6) Proportion of adults (>15 years) with fever in the past 2 weeks treated with any antimalarial by source of provider (3.7) Proportion of households in poor areas with one or more inhabitants with fever in the past 2 weeks treated with ACTs, by source of provider (3.8) Proportion of households in poor areas with one or more inhabitants with fever in the past 2 weeks who received ACT treatment within 24 hours of fever onset, by source of provider (3.9) Proportion of households in poor areas with one or more inhabitants, with fever in the past 2 weeks treated with any anti-malarial, by source of provider Notes: (a) These indicators will be disaggregated by the socio-economic status of households. Wherever feasible, measures of absolute poverty (based on country poverty lines) will be used in preference to measures of relative poverty (see Section 6.6. for rationale). Administrative areas may be classified based on relative poverty and sampled accordingly. Survey participants will be requested to provide self-reported responses to questions regarding household assets. For measures of relative poverty, either household income quintile or household wealth quintile will be used for disaggregation. (b) The indicators of use will also be disaggregated by provider compliance with prescriptions of correct dosages for the right duration, and by patient compliance with consumption of correct doses for the right duration.
Q 4.1 Has the AMFm mechanism helped increase the market share[5] of quality assured ACTs relative to all anti-malarial treatments in the public, private for-profit and not-for-profit sectors in rural/urban areas?	(4.1) Total volume of ACTs sold or distributed in the last week, as a proportion of the total volume of all anti-malarials sold or distributed in the last week, via outlets across sectors in rural /urban areas (by manufacturer) (4.2) Quantity of ACT procured by first line buyers ('unit' = boxes of ACTs by type and dosage)
Q 5.1 What are the plausible effects of the AMFm Phase 1 on ACT market dynamics (trends in, interactions among, and factors influencing demand, supply and price of ACTs) at the regional and global levels?	The Independent Evaluator will be responsible for defining the indicators, specifying data sources, conducting analyses and writing the report. The key conditions are that: (i) the methods must be endorsed by a group of independent reviewers *with world-class expertise and recognition in studies of market dynamics*, and (ii) the approach must not impose undue burden of data collection on the countries.

Evaluation Questions	Indicators
Q 6.1 This study will define functions, institutional and financial requirements for a potential global roll out of the AMFm, with emphasis on the following question: "What will it take to run a global phase of the AMFm?" It will identify options for managerial and institutional systems and structures for a potential global roll out of the AMFm.	The Independent Evaluator will be responsible for defining the indicators, specifying data sources, conducting analyses and writing the report. The key conditions are that: (i) the methods must be endorsed by a group of independent reviewers *with world-class expertise and recognition in institutional analysis*, and (ii) the approach must not impose undue burden of data collection on the countries.

Note: This table will be expanded further to specify the full definition (numerator and denominator) of each indicator by method of data collection (e.g., household/outlet survey).

[1] The quality of drug storage conditions and drug expiry dates will also be assessed during outlet surveys.

[2] The term private sector includes both the formal and informal private sector.

[3] The independent evaluation will disaggregate "patients" in terms of those who report having had access to biological diagnosis of malaria (i.e., microscopy or rapid diagnostic tests (RDTs)) versus those who did not.

[4] The classification of ACT by quality assured vs. non-quality assured will be determined insofar as possible; self-reported results from household surveys will present a challenge.

[5] "Market share" here is defined in terms of a proportion of stocks in outlets, proportion of purchases based on exit interviews and proportion of treatments used as reported from household surveys, with the emphasis being on findings from household surveys. Stocks in outlets tell us what such outlets can dispense or sell; consumers can only buy what is available for sale. The findings must be interpreted with caution with regard to factors influencing stock levels and mix of products at retail outlets. Exit interviews can tell us whether or not ACTs are increasing as a proportion of purchases at those outlets. This is useful, but it does not tell the full story. Such data is from a self-selected sample (i.e. those who choose to use private drug shops). These interviewees differ in some ways, known or unknown, from those who do not use the private shops. By definition, the samples have a selection bias. A problem arises when one tries to analyze the data by socio-economic status (SES), part of the "reaching the poor" question. Data from exit interviews at private sector outlets help to answer the following question: *"What is the SES distribution of those who use anti-malaria treatment from private drug shops under study?"* It does not answer the following question: *"What is the SES distribution of those who use anti-malaria treatment from <u>any</u> source*?" In order to answer the latter, it is important to include data from household surveys, and from other facilities, in addition to private drug shops.

Refer to Annex 1 to see how AMFm objectives, evaluation questions and some illustrative indicators, at the output and outcome level, map onto each other.

6.5 Methods of the Independent Evaluation

Data will be collected via baseline and end point surveys of:

(a) Outlets (public and private); and

(b) Households.

The independent evaluation will also draw upon evidence generated by other components of the M&E Framework (e.g. country monitoring of supporting interventions, operational research, additional relevant contextual information).

Wherever possible, outlet surveys will include formal and informal outlets to provide a comprehensive report. Surveys of informal outlets may be constrained in some settings by a lack of reliable sampling frames (e.g., mobile vendors). In such instances, household surveys will provide information about the sources of malaria medicines used by respondents.

Outlet surveys will be used to gather data about ACT price, availability, use and the 'market penetration' of ACTs in relation to monotherapies and other undesirable anti-malarial treatment products. The quality of supply chain services (e.g., drug storage conditions and drug expiry dates) will also be examined. Findings from these surveys will yield information about whether **'supply side'** objectives of AMFm have been met, and ACTs have become more widely available and affordable in countries.

Household surveys will be conducted to examine the nature and extent of ACT uptake, over the Phase 1 period. Household data will be examined by age and socio economic status, to explore ACT use and coverage by sub-groups, including the poor, rural residents, and children less than 5 years of age.

Both the household and outlet surveys will provide information on factors that influence demand. For example, information campaigns aimed at households influence demand. Information provided to service providers in pharmacies and drug shops can also influence demand because these workers influence choices made by patients who come to the pharmacies and shops; this was the case in the pilot experiment conducted in Tanzania by the Clinton Foundation, and is consistent with the literature on supplier-induced demand.

Given the limited implementation period of AMFm Phase 1, and notes from the Five-Year Evaluation (see Section 1.1), short-term expectations about population-wide shifts in ACT use need to be realistic because of:

- A time lag between ACT availability and change in user behavior, i.e., given that health seeking behavior takes time to change.
- A short "observation window:" AMFm Phase 1 offers only one malaria season in many countries within which to observe behavior change.

Table 9 builds on this further by describing proposed methods and frequency of data collection, along with stakeholder responsibilities for each indicator.

Table 9: Data Collection Methods, Frequency and Responsibilities

Evaluation Question	Indicator	Method of Data Collection	Frequency	Responsible for Data Collection	Countries Involved
Evaluation Question 1: ***ACT Availability***	Indicators 1.1 – 1.5	Outlet surveys: standardized questionnaire	Twice: baseline and end point (approx 12-15 month interval)	Survey Contractors	AMFm countries + Comparator non-AMFm countries
Evaluation Question 2: **ACT Affordability**	Indicators 2.1-2.4	Outlet surveys: standardized questionnaire + mystery client shopper + 'exit' interviews (where appropriate) Household surveys: standardized questionnaire	As above	Survey Contractors	As above
Evaluation Question 3: ***ACT Use***[1]	Indicators 3.1-3.10	Household surveys: standardized questionnaire *Note: Outlet survey exit interviews may provide supplementary data. Due to inherent selection bias such data must be interpreted with caution.*	As above	Survey Contractors	As above
Evaluation Question 4: ***ACT market share:*** *"Crowding Out" Undesirable Anti-Malarial Treatments*	Indicators 4.1-4.3	Outlet surveys: standardized questionnaire[1] Household surveys	As above	Survey Contractors	As above

[1] Triangulation or corroboration of market trends with other data sources should be explored. For example, trade import and production volumes for artemisinin monotherapies and other ineffective treatments, such as chloroquine, should be sought, where possible. These data will have limits, given local manufacturing of such drugs (i.e., volumes not comprehensively covered by import registers), coupled with the time limited nature of AMFm Phase 1, and lag time required for market shifts to occur (also given seasonality aspects of malaria). Nonetheless, all available data sources should be considered when compiling a situational analysis.

6.6 Data Analysis & the Independent Evaluation Report

Data analysis from the independent evaluation determines to what extent the AMFm achieves its objectives, outputs and outcomes. The analysis will be undertaken by an independent contractor(s), and will include summary and descriptive statistics, such as:

- Numbers of outlets and households surveyed;
- Indicator data compared across time (end point versus baseline) by:
    - Group (intervention versus comparator countries);
    - Sub-group analysis using population variables such as urban/rural, and socio-economic status. Wherever feasible, measures of absolute poverty (based on country poverty lines) will be used in preference to measures of relative poverty. Administrative areas may be classified based on relative poverty and sampled accordingly. Survey participants will be requested to provide self-reported responses to questions regarding household assets. For measures of relative poverty, either household income quintile or household wealth quintile will be used for disaggregation. It should be noted that classification by quintiles (relative poverty) *alone* is useful but potentially misleading. This is because in low-income countries of sub-Saharan Africa, for example, even households in middle quintiles are often poor in absolute terms. If relative classification alone were used, that approach might exclude from policy discussion the plight of those who are poor in absolute terms (and would benefit from co-paid ACTs) but comparatively better off than the poorest in the same society. It would also ignore the objective of delaying resistance to artemisinin. If those who are poor in absolute terms (but in the middle or upper income quintiles on a relative basis) use artemisinin monotherapy, that practice will increase the risk of drug resistance -- and that is a "public bad" that applies to all. In addition, the short duration of Phase 1 may constrain the maturation of supporting interventions and, consequently, the extent of penetration of co-paid ACTs among the poorest of the poor. The level of effort required is such that it may not be possible to collect household consumption data for assessing absolute poverty. Proxy measures will be explored. [One issue that was discussed extensively by the AMFm Task Force in the design phase was the definition of poor people, and it was agreed that in this context, the focus should be on the lower 60% of the population, or the absolutely poor (e.g., living on less than $2 per day).]

Indicators will be standardized before data collection. Subsequently, the analyst must detail methods used to adjust for heterogeneity in sampling methods (if such heterogeneity proves inevitable), as well as their limitations and implications for comparability.

An assessment of 'red flags' (see Chapter 7) will be required, as well as the completion of multi-variate analyses controlling for confounders, as and when appropriate, within the study design. The Independent Evaluator will be required to submit a proposed analysis plan, as part of their bid application (including power calculations and suggested "dummy tables"). Other components of the M&E Framework (e.g., OR, special studies, etc.) will inform the findings of the Independent Evaluation. These findings will assist the interpretation of independent evaluation.

6.7 Data Quality

Table 10 summarizes data quality responsibilities for the Independent Evaluation.

Table 10: Data Quality Responsibilities for the Independent Evaluation

Framework Component	Responsibility for Data Quality	Types of Data Quality Tools & Measures
Baseline & End Point Surveys	(a) Survey contractors Survey contractors will be obliged to allow access to all survey data sets, and hard copies of survey questionnaires (as requested) by the contractor(s) undertaking the meta-analysis. (b) Independent Evaluator The independent evaluation contractor undertaking meta-analysis of country data is responsible for audit type checks on survey data to assess validity. (c) The AMFm Ad Hoc Committee has oversight responsibility.	(a) Survey contractors will be required to explain their data quality procedures as part of contract appointment criteria. Also, survey contractors under the scrutiny of the independent evaluation contractor undertaking the meta-analysis, will ensure a standardized approach to the survey protocol, including data quality assessments.

6.8 Going Global: Market Impact and Institutional Analysis

There are two other items of strategic importance to the Global Fund Secretariat in relation to the Independent Evaluation of the AMFm Phase 1 and a potential global roll out. Findings from these studies will inform the evaluation about selected and system-wide effects of the AMFm Phase 1, other than its central objectives. The following two studies were selected on the basis of their critical importance for the broad ACT market and for informing institutional approaches to a potential global roll out of the AMFm.

6.8.1 Market Impact Study

This study will examine the plausible effects of AMFm Phase 1 on ACT market dynamics (trends in, interactions among, and factors influencing demand, supply and price of ACTs) at the regional and global levels. It is acknowledged that the *global* market impact of the AMFm Phase 1 may be limited due to: (1) the time limited nature of the AMFm Phase 1; and (2) the relatively small number of countries involved in Phase 1 from a global market stance.

This study has two objectives:

Objective 1: is to assess if the supply of Active Pharmaceutical Ingredient (API) and ACTs is able to meet the demands of a potential AMFm global roll out. If the supply of API and finished product is not able to keep up with the demand for ACTs then, all else being equal, financing a rapid increase in ACTs will only lead to inflation in the price of the drugs. This is true whether or not the financing mechanism is AMFm or any other mechanism. If, however, supply is relatively elastic, there will be fewer concerns about inflation of ACT prices as AMFm moves to a general phase covering more countries.

There are five supply indicators and two sets of demand indicators that could be used to measure these dynamics. The supply indicators are:

- Acreage of *Artemisia annua* planted
- Quantity of artemisinin extracted
- API prices
- ACT finished product wholesale prices (by age category)
- ACT production capacity across all firms with qualified products

Demand indicators would include ACT retail prices in Phase 1 countries as well as retail prices in neighboring countries to see the spillover effects of the AMFm.

Objective 2: is to understand the market dynamics of artemisinin monotherapies to see if the AMFm is helping reduce the supply of these monotherapies. A useful exercise is to monitor wholesale and retail prices of AMT.

6.8.2 Institutional analysis

This study will define functions, institutional and financial requirements for a potential global roll out of the AMFm, with emphasis on the following question: "What will it take to run a global phase of the AMFm?" It will identify options for managerial and institutional systems and structures for a potential global roll out of the AMFm.

These studies will be included in the Request for Proposals for the Independent Evaluation.

6.9 Independent Evaluation & Stakeholder Roles and Responsibilities

Table 11 summarizes key stakeholder responsibilities.

Table 11: Stakeholder Responsibilities for the Independent Evaluation

Stakeholder	Independent Evaluation & Key Responsibilities
AMFm Phase 1 Countries	• Facilitate contractor(s) undertaking independent evaluation. Countries have no direct responsibility for undertaking the independent evaluation • Use findings from the independent evaluation to inform National Malaria Control Program activities
Data collection contractors undertaking baseline and end point surveys in countries for the Independent Evaluation	• Collect survey data according to protocol requirements
Independent Evaluator	• Facilitate a standardized approach to the survey protocol undertaken by the survey contractors • Complete meta-analysis of country data • Assess counterfactual situation (in 2-3 non AMFm countries) • Assess red flag status • Complete data quality control checks • Write report with recommendations

Stakeholder	Independent Evaluation & Key Responsibilities
Global Fund Secretariat	• Commission the independent evaluation • Manage contractual arrangements of the Independent Evaluator and the companies undertaking baseline/ end point assessment • Seek independent technical advice from an Expert Advisory Group (EAG) and the Roll Back Malaria Monitoring and Evaluation Reference Group (MERG) as appropriate • Support the work of AMFm Ad Hoc Committee and, in that context, the work of the TERG regarding the independent evaluation under oversight of the AMFm Ad Hoc Committee
Expert Advisory Group	• Advise the Global Fund Secretariat on the technical soundness of key deliverables related to AMFm (including the M&E Technical Framework, inception and final reports from the Independent Evaluator, and other mission-critical technical tasks as may be requested by the Global Fund Secretariat)
Technical Evaluation Reference Group	• Provide guidance with regard to the technical parameters of the design of the independent evaluation of the AMFm, under the oversight of the AMFm Ad Hoc Committee. Interactions between the TERG and the Independent Evaluator shall take place within the context of meetings convened by the AMFm Ad Hoc Committee.
AMFm Ad Hoc Committee	• Per Board mandate, provide oversight for the independent evaluation • Report to the Global Fund Board the Committee's findings on the independent evaluation
Global Fund Board	• Decide whether to expand, accelerate, terminate or suspend the AMFm based on independent evaluation findings and the report of the AMFm Ad Hoc Committee

6.10 Dissemination of Findings: Independent Evaluation

The report from the Independent Evaluation will be available to the Global Fund Board, along with a report from the AMFm Committee which makes recommendation(s) to the Board, on the future direction of AMFm within the Global Fund, based on evidence from the evaluation. These documents will be available to the general public via the Global Fund website, per normal Global Fund practice.

6.11 Strengths, Limitations and Comparisons

6.11.1 Comparison between AMFm Phase I countries and non-AMFm countries

Comparing the ACT situation (i.e., regarding availability, price, use, and "crowding out AMTs") between AMFm and non-AMFm countries is a design strength. An ideal study design would have been a prospective, *randomized* study with a comparison between an intervention and a "comparison" group of countries. In this case, randomization was not possible because of:

(a) *The need for geographic clustering of countries*: Due to a limited number of countries participating in AMFm Phase 1, it was necessary to include countries in geographic clusters (where possible). This attempts to minimize the diversion of co-paid ACTs from AMFm countries across borders to non-AMFm countries, (i.e., a risk of AMFm Phase 1 because there are incentives for agents in the supply chain to profit from subsidized ACTs).

(b) *Country choice*: Countries may or may not choose to apply to the AMFm; they are active participants rather than passive subjects in the selection process.

In this case, the potential limitations of non-randomization are those of internal validity (i.e., if a study can plausibly demonstrate a causal relationship between an intervention and an outcome, then it is said to have internal validity). The use of an unmatched or nonequivalent comparative group helps to reduce the uncertainty about what would have happened in the absence of AMFm, by allowing a comparison of ACT availability, affordability and use in countries, where AMFm is not being implemented. This allows inferences about the "added value" of AMFm to be made, with caveats (i.e., observations cannot be attributed as causal). The reader is referred to the literature on quasi-experimental study designs for more details on these considerations.

6.11.2 Comparison between AMFm and the traditional business line at the Global Fund

Benchmarking: For all items related to service delivery and quality of care, the AMFm will be assessed against its objectives within the bounds of national treatment guidelines and WHO guidelines. For all counterfactuals, the benchmarks will be real-life counterfactuals on the same scale and measured by the same indicators within the same period of implementation.

The Independent Evaluator will assess the extent to which AMFm Phase 1 meets its objectives. In addition, the Independent Evaluator will draw comparisons between the AMFm and alternative financing platforms that support access to antimalarials on a large scale in multiple countries. The comparison will use similar measures of (i) affordability, (ii) accessibility, (iii) use, (iv) market share and (v) cost-effectiveness.

The principal alternative financing platform to which the AMFm Phase 1 will be compared is the Global Fund's traditional (rounds-based, non-AMFm) approach to financing. The Global Fund is a financing mechanism that supports multiple, country-led approaches to service delivery, not an implementing agency that is dedicated to a particular mode of service delivery. Therefore, comparison will be made between the traditional financing platform (i.e., the round-based system of grants) and the new financing platform (the AMFm), both of which support multiple, country-led approaches to service delivery.

The Independent Evaluator will compare the traditional approach and AMFm Phase 1, using similar measures of performance that are presented in Sections 6.3 and 6.4. Traditional grants approved by the Global Fund Board at about the same time as those under the AMFm could provide suitable comparators of performance during a *concurrent* time period.

The Independent Evaluator will also compare the historical trajectory of performance under traditional grants with the trajectory of performance under the AMFm.[34] The Independent Evaluator will have access to the complete data set from which the conclusions of the Five-Year Evaluation on ACT access were drawn, for the purpose of facilitating comparative analyses in a timely and transparent fashion.

Direct comparisons between performance under the traditional and AMFm financing platforms will provide opportunities to decide which approach (or combination of approaches) to financing better

[34] *The implementation period of AMFm Phase I includes only 12 to 15 months between the baseline and end point assessments. Therefore, a head-to-head comparison of the trajectories is probably generous to the traditional model because the countries assessed in the Five-Year Evaluation had more than 12 to 15 months of implementation.*

serves the twin objectives of expanding access to ACTs and displacing undesirable monotherapies from the market. The reports of all comparative analyses will be available in the public domain.

6.11.3 Direct comparisons between AMFm and other (non-Global Fund) financing platforms

In addition to comparison with the traditional business line at the Global Fund, to the extent that data are available or can be collected within budget, the Independent Evaluator of the AMFm will compare progress in scaling up ACT use and reaching vulnerable groups with findings from other financing platforms for scaling up ACTs. These may include multi- or bilateral financing platforms. The Booster Program for Malaria Control at the World Bank, the U.S. President's Malaria Initiative (PMI) and other bilaterally or multilaterally funded initiatives are potential comparators, provided that they are multi-country initiatives, measured using the same indicators, in the same time frame (i.e., duration of implementation) as AMFm Phase 1, and are subject to the same peer-review process. *Officers in charge of potential comparators may decline the opportunity to participate in this direct comparison. In such instances, no evaluation report on such initiatives will be admissible when the report of the Independent Evaluation of the AMFm is prepared. Separate evaluations commissioned by such initiatives will not be admissible because there is no guarantee of comparability of methods, skill-sets of evaluators, peer review processes and transparency.*

The direct comparisons will use similar measures of (i) availability, (ii) affordability, (iii) use, and (iv) market share of ACTs and (v) cost-effectiveness. Since a key objective of the AMFm is to displace oral artemisinin monotherapies (as well as CQ and SP) from the market, direct comparisons must include the extent to which non-AMFm mechanisms displace oral artemisinin monotherapies (as well as CQ and SP) from the market.

The following criteria will guide the admissibility and conduct of comparisons:

- **Structure and definition:** They will not compare a financing platform against a single mode of service delivery. They may compare a single mode of service delivery financed by Platform A against the same mode of service delivery financed by Platform B, or the entirety of work (on ACTs) financed by Financing Platform A against the entirety of work financed by Platform B.

- **Scope:** Comparisons will address the questions specified in Table 6 (AMFm Objectives by Independent Evaluation Questions) to cover the objectives of (i) "saving lives" by improving access to timely and effective treatment with ACTs; and (ii) "buying time" (displacing AMTs from the market), and the cost of doing so. Each objective is necessary, but neither is sufficient for global public health goals. A potential comparator that addresses only one objective but not the other will not be admissible.

- **Duration and maturation:** The time from initiation to assessment must be the same for the AMFm Phase 1 and the comparator. Specifically, this means the first 12-15 months of the AMFm Phase 1 and the first 12-15 months of each comparator.

- **Scale:** Comparators must be on *at least the same scale* and present at least the same contextual diversity as the AMFm Phase 1. Tightly controlled pilots, or operations in only a few districts or only a small country, will not be admissible as comparators -- whether funded by multilaterals or bilaterals. It would be easier to find a small-scale comparator than a large-scale comparator, but this is not appropriate for the relevant policy discussions. This is because small-scale projects do not include the complexity and diversity of scaling up, which AMFm Phase 1 would include. Therefore, their cost structures do not necessarily

reflect the cost structures of large-scale efforts. The Global Fund Board wanted a large-scale Phase 1 of the AMFm to inform its decision. Otherwise, the pilot ACT subsidy experiment in Tanzania, (which was commissioned by the Clinton Foundation and illustrated the potential of the AMFm), might have sufficed for a decision to go to a global roll out of the AMFm. That pilot experiment in Tanzania, not a large-scale Phase 1, is perhaps a reasonable basis for comparison with small-scale, non-AMFm initiatives. In order for comparators to be meaningful, they should be on a similar scale as the AMFm Phase 1.

- **Methods and transparency:** Evaluation methods must be similar for AMFm Phase 1 and the comparator, and all datasets must be subject to the same level of peer review and public access. Any potential comparator that does not meet these criteria will be rejected because of a lack of transparency. Similarly, if the staff of any financier are unwilling or unable to provide verifiable responses to questions from the evaluators, and to have such responses posted in the public domain, the comparator under examination will be rejected.

- **Costs, effectiveness and benefits:** Where costs and benefits are compared, such comparisons will use the same methods to calculate net costs and net benefits attributable to each platform. Where feasible, both the attributable costs and attributable benefits will be monetized to enable not just a cost-effectiveness analysis but an explicit cost-benefit analysis.

Box 6: Expert reflections on cost-effectiveness: Text extract from *Buying Lives, Saving Time*

"Cost-effectiveness analysis is an inexact science, more so in cases, such as this one, where many assumptions must be made on scant data. Uncertainty bounds are very wide… One important aspect, relevant to ACTs, is that cost-effectiveness analysis does not address the total cost of an intervention for a country. Something that is very cost effective—because it costs little and works well—could be very expensive per capita if a large proportion of the population needs it, which is the case for malaria treatment. It may not be affordable without additional resources, even though it is desirable and relatively cost-effective……"

Arrow, K., Panosian, K., Gelband, H. *Saving Lives, Buying Time*. 2004. Page 67.

6.11.4 Architecture of the Independent Evaluation

On balance the architecture of the Independent Evaluation is a strength. Ideally baseline and end point AMFm country surveys should be undertaken by the same investigator(s) to minimize inter-observer variability. This is not possible for reasons of pragmatism, efficiency and the reduction of duplication (Table 12). A number of organizations are already undertaking ACT market surveys (Table 13), and this expertise and data will be drawn upon, as much as possible, for the evaluation of AMFm Phase 1. For these reasons, data collection in AMFm countries will be undertaken by different organizations, and separated from the meta-analysis of country data. All or some combination of these organizations, plus possibly some others, will be commissioned by the Global Fund to undertake baseline survey data collection and end point data collection for both outlets and household level surveys, in line with specified indicators and a common protocol. If an individual organization chooses not to engage, efforts will be made to access and use any relevant secondary survey data that is already gathered (particularly for informing baseline setting).

Table 12: Advantages & Disadvantages of Separating Data Collection from Data Analysis

Advantages	Disadvantages
• **Capitalize on available ACT survey data** • **Avoid duplication** (i.e., by repeating surveys where existing data exists) • **Feasibility** (i.e., it is not feasible to undertake primary data collection for outlet and household surveys, in up to 14 countries[1], in twelve months) • **Saves money**	• **Inter-observer variability**: This will be mitigated by standardizing indicators and datasets before the baseline assessment. • **Reduced competition** (i.e., direct commission not competitive tendering)

[1] Up to 11 countries are eligible to participate in AMFm Phase 1 and 2 to 3 comparator countries not participating in AMFm Phase 1 will also be included to examine the counterfactual situation.

Steps can be taken to mitigate or control identified disadvantages. For example, a *manual of operations* that sets out standard procedures for sampling, interviewer training/supervision, survey instruments, indicator definitions, and data management methods, will help control inter-observer variability. Such a manual will be the responsibility of the Independent Evaluator to produce in consultation with the organizations undertaking baseline/end point surveys.

Table 13: Organizations Conducting ACT Market Surveys

	ACTwatch	MMV[1]	HAI Global Network[2]
Countries where ACT market surveys are being conducted[3] *(√ = AMFm eligible countries)*	• Benin √ • Cambodia√ • Democratic Republic of Congo • Madagascar √ • Nigeria √ • Uganda √ • Zambia	• Uganda √ • Malawi • Senegal √	• Ghana √ • Kenya √ • Nigeria √ • Senegal √ • Tanzania √ • Uganda √

[1] MMV works in partnerships in 38 countries globally; pricing surveys have been (or are planned to be) conducted in the highlighted AMFm countries, as well as other non-AMFm countries.

[2] The joint WHO/HAI Project on Medicine Prices and Availability was launched in 2001. The WHO/HAI manual is now recognized as the gold standard in measuring medicine prices and availability. Over 55 national or provincial surveys have been conducted by governments, researchers, civil society groups, and others across the world. Survey data is available for the indicated AMFm Phase 1 countries [*Note*: the completeness of this list, along with how recent the survey data is needs to be assessed].

[3] Niger and Rwanda are two AMFm Phase 1 countries that are *not* currently covered by these ACT surveys

6.11.5 Sampling Challenges

Survey sampling will be given special attention to ensure national representativeness. The use of area and stratified sampling methods will be employed to ensure demographic, socio-economic and geographic representation. Sampling frames, sample size and power calculations are challenging in a number of respects. For instance, the availability of sample frames for private sector providers will be variable, and possibly limited in some settings, both within and across countries. Where such information is scant, it is likely that area sampling strategies will need to be employed, and tactics such as the mapping of outlets for anti-malarial treatment distribution or purchase (in all sectors) undertaken.

6.11.6 Malaria Seasonality

It is best to conduct the surveys during malaria season and every effort will be made to do so, where possible. However, for several countries, this may not be possible given the Phase 1 timetable. Where this occurs, baseline and end point data collection will be scheduled at the same time of year to ensure the validity of between survey data comparisons. The geographic dispersion of countries means that they all cannot be in peak malaria season at the same time.

6.11.7 Generalisability

In a strict sense, findings from the Independent Evaluation cannot be generalized beyond the countries from which the intervention and "non-equivalent control" comparisons are derived, due to a range of inter-country differences (i.e., low "external validity"). Whilst recognizing this, this is also a sizeable evaluation that "road tests" the AMFm concept, and draws upon experience from a range of country settings to inform any subsequent global scale up or modification to the AMFm model. Therefore, some of the lessons from Phase 1 may be adaptable for use in other countries in the event of a global roll out of AMFm.

7. MARKERS OF "CLEAR FAILURE (RED FLAGS) IN THE AMFm DESIGN"

KEY MESSAGES

- The Global Fund Board defines "red flags" as "clear failures in AMFm design." The presence or absence of red flags will inform the Global Fund Board's decision to expand, modify or terminate the AMFm.
- Three red flags are proposed: **ACT price** violations; lack of **ACT availability;** and **failure to gain market share**.
- The reader is encouraged to review carefully the contents of Chapter 1, and the questions and rationale discussed in this chapter, in order to put in context the choice of "red flags."
- The timeline in this Technical Framework is based on Global Fund Board decisions in effect as of July 2009. The choice of "red flags" includes a pragmatic consideration of that timeline.

7.1 Background and Purpose

Red flags signal "clear failures" in the design of AMFm, per decision of the Global Fund board (see Box 7 below). They serve to facilitate Global Fund decision making, in that their presence or absence will help decide whether to expand, modify or terminate the AMFm beyond Phase 1.

Box 7: Global Fund Board Decision Point (GF/B17/DP8). Annex 1 to: Principles for AMFm Policy Framework, Implementation & Business Plan

The timing of the AMFm launch and implementation in endemic countries should be developed on the basis of the phase-in paper set out as Attachment 3 to the PSC Report (GF/B17/4), to include the following factors:

- A phased launch starting with a first group of countries to be selected according to criteria developed by the Secretariat and agreed at the 18th Board Meeting;
- Roll out of the AMFm in these selected countries for an initial phase until a Board decision on full roll out is reached;
- Operational research and extensive M&E efforts carried out in these first countries accessing the AMFm to assess the extent to which the AMFm can meet its objectives and provide lessons learned about the design and implementation of the AMFm that would inform a subsequent Board decision on full roll out;
- An independent technical evaluation of the roll out of the AMFm in the selected countries will be commissioned by the Global Fund Secretariat, under the guidance of the appropriate committee, using a set of predefined key indicators to be further elaborated and agreed at the Eighteenth Board Meeting to assess potential failures and shortcomings ("red flags") in the AMFm;
- At its first meeting in 2010, the Board will consider findings from this evaluation for a decision on whether to expand, accelerate, terminate or suspend the AMFm business line;
- Expansion from the initial phase to a full roll out in all eligible countries will occur within a year of launch unless clear failures ("red flags") in the AMFm design are observed.

In May 2008, the Board of the Global Fund changed from 2010 to 2011 the date of the Board's decision on the future of the AMFm, which will be based on the independent evaluation. The rest of this chapter is based on the Board decisions cited above.

These red flags are prospectively defined and informed by baseline data, as much as possible (see below). They serve to facilitate Global Fund decision making, in that their presence or absence will help decide whether to expand, modify or terminate the AMFm beyond Phase 1.

7.2 What is a "Red Flag"?

- It is important to note at the outset that the Independent Evaluation will include all parameters and indicators specified in Chapter 6. This section is about which of these can reasonably be judged as a "clear failure in the AMFm design" within a 12-month period,[35] and how those should be measured; it is in addition to, not instead of, Chapter 6.

Failure to achieve results may be due to design failure, implementation failure, or a combination of the two. A "clear failure in the AMFm design" could be hard or impossible to overcome despite strong efforts during implementation. Red Flag status will be assessed at the end of the implementation period to inform the Board's decision.

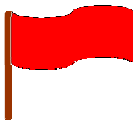
The AMFm consists of two components. One component is a price reduction through a combination of manufacturer negotiations and a "buyer subsidy" for ACTs that operates via a "co-payment"[36] at the top level of the procurement and supply chain to malaria endemic countries. The other component is a combination of activities called "supporting interventions" to assist the safe and effective implementation of the AMFm. The Board of the Global Fund has decided that they will be implemented in combination, not separately, during AMFm Phase 1.

Component 1: Price reduction through manufacturer negotiations and a 'co-payment'

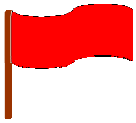
This is the innovation at the core of AMFm as a new business line at the Global Fund. If strong efforts are made to implement this component, there should be demonstrable evidence of price reductions within the implementation period of fifteen months. The timeline under discussion is as follows: After a Global Fund Board Decision in November 2009, baseline assessments will be done in December 2009, co-paid ACTs will reach the countries by March 2010 and the end point assessments will be done no later than June 2011.

The approach to price reduction has no large-scale precedent within the global health architecture of development assistance for malaria control; hence, the appropriate questions are straightforward: "Did it work?" and "To what extent did it work?"

Accordingly, two red flags are proposed for this component of the AMFm:



Price – Failure to achieve significant reductions in the retail prices of ACTs.



Availability – Serious lack of availability of co-paid ACTs despite strong efforts to ensure availability (i.e., a failure of design, not a weakness of execution).

[35] *A 12 month timeframe is likely insufficient to observe demonstrable changes in how well co-paid ACTs will reach vulnerable populations in the short term.*

[36] *The AMFm will pay a portion of the ACT price alongside payment paid by eligible first line buyers in malaria endemic countries. This ACT cost sharing arrangement between the AMFm and country first line buyers is termed a 'co-payment.'*

Component 2: Supporting interventions

Supporting interventions include public education and awareness campaigns; provider training, monitoring and supervision to ensure patient safety; pharmacovigilance; regulatory preparedness; and efforts to expand access to treatment among vulnerable populations such as poor people, children and those living in remote locations.

Several questions were considered in defining red flags for this component of AMFm Phase 1. The reader is encouraged to review these carefully in order to put in context the choice of red flags:

- What is known from the independently evaluated effect of the traditional business line? There is recent evidence of the extent to which the traditional business line has worked over a five-year period. These are noted in Box 1 (Introduction).

- Which of these supporting interventions is unique to the AMFm? None of these supporting interventions is an AMFm innovation. Many of them are part of familiar approaches to development assistance for malaria treatment, which the international community finances through the traditional business model of the Global Fund. Regardless of the AMFm, some of them are among the stewardship and public health roles of the government (e.g., pharmacovigilance) and public policy to promote equity (e.g., efforts to expand access to treatment among vulnerable populations). Regardless of the AMFm, governments should care to know and be willing to spend public funds to improve what is going on in the private sector; the emergence of resistance to artemisinin because of widespread AMT in the private sector would jeopardize ACTs in the public sector.

- What is the median time from initiation to effectiveness of supporting interventions financed through and governed by the same multilateral channels as AMFm Phase 1? The purpose is to establish a benchmark for comparison of AMFm Phase 1 performance during a 12 month period. This would not provide evidence of a Red Flag, since it would measure speed and effect of execution rather than design -- and a Red Flag is about "clear failure of AMFm design." However, it is a useful topic for discussion of findings from Chapter 6. The AMFm includes an innovation in the form of co-paid ACTs. There is a large body of literature on the diffusion of innovations[37], and this is relevant to a rational interpretation of findings on the extent to which AMFm Phase I achieves, within a 15-month period, increased access to ACTs among vulnerable populations. A relevant concept is how fast and how well an innovation diffuses through the adopter categories of "innovators", "early adopters", "early majority", "late majority" and "laggards?"[38] For the purpose of interpreting findings from Chapter 6, the relevant questions are as follows:
    - How fast and how effectively has the traditional business line of the Global Fund grants enabled the move of ACT treatment through the adopter categories of "innovators", "early adopters", "early majority", "late majority" and "laggards"?

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[37] *See among others:*

a) Becker, M. Factors affecting diffusion of innovations among professionals. AJPH. 1970. Volume 60, N. 2.

b) Dearing, J. Improving the state of health programming by using diffusion theory. J Health Commun. 2004;9 Suppl 1:21-36.

c) Rogers, E. M. 1995, Diffusion of Innovations, Fourth ed., The Free Press, New York.

d) Tornatzky LG, Klein KJ. Innovation characteristics and innovation adoption implementation: a meta-analysis of findings. IEEE Transactions on Engineering Management 1982; 29: 28-45.

e) Greenhalgh T, Robert G, Macfarlane F et al. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. Milbank Quarterly 2004; 82: 581-629.

[38] *'Laggards' are defined as the last 16 percent of individuals in a system to adopt an innovation.*

- Compared to the traditional business line, how fast and how effectively has the AMFm enabled the move of ACT treatment through the adopter categories of: "innovators", "early adopters", "early majority", "late majority" and "laggards"?

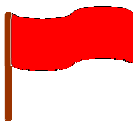
An intense approach to the implementation of supporting interventions can help to speed up the "diffusion" process during AMFm Phase 1. Therefore:

- If supporting interventions in the AMFm perform worse during its first 12-15 months than those in the traditional business line did over their initial 12-15 month period, that would be a failure of execution (relative to the benchmark, which uses much the same supporting interventions) but not a failure of design.

- If supporting interventions in the AMFm perform at least as well as the traditional business line did during their initial 12-15 month period, the AMFm cannot rationally be pronounced a failure of design (or execution) unless the traditional business line is similarly pronounced a failure of design (or execution).

Combination of Component 1 and Component 2

What is a reasonable definition of a "red flag" that combines the two components of AMFm, and which may be meaningful after 12-15 months of implementation?



Failure to gain market share – "Market share" refers to ACTs as a proportion of all anti-malaria treatments (including ACTs, CQ, SP, AQ and oral AMTs).

In broad terms, "market share" here is defined in terms of a proportion of stocks in outlets, proportion of purchases based on exit interviews and proportion of treatments used as reported from household surveys, with the emphasis being on findings from household surveys.

Stocks in outlets tell us what such outlets can dispense or sell; consumers can only buy what is available for sale. The findings must be interpreted with caution with regard to factors influencing stock levels and mix of products at retail outlets.

Exit interviews can tell us whether or not ACTs are increasing as a proportion of purchases at those outlets. This is useful, but it does not tell the full story. Such data is from a self-selected sample (i.e., those who choose to use private drug shops). These interviewees differ in some ways, known or unknown, from those who do not use the private shops. By definition, the samples have a selection bias. A problem arises when one tries to analyze the data by socio-economic status (SES), which is part of the "reaching the poor" question. Data from exit interviews at private sector outlets help to answer the following question: *"What is the SES distribution of those who use anti-malaria treatment from private drug shops under study?"* It does not answer the following question: *"What is the SES distribution of those who use anti-malaria treatment from any source?"* In order to answer the latter, it is important to include data from household surveys, and from other facilities, in addition to private drug shops.

This red flag must be treated with great caution. As noted in the report of the Five-Year Evaluation, there may be a lag between financial disbursements and measurable changes at the level of the outlet. That same cautionary note applies to the Independent Evaluation of AMFm Phase 1.

7.3 Alternatives Rejected and Reasons for Rejection

- No red flag at all: The rationale for this option is that red flags may be subject to misinterpretation, leading to a wrongful refusal to go to a global phase of the AMFm (i.e., a false negative conclusion). This was rejected because it is important to demonstrate that not only was a serious effort made to execute the design of AMFm, but that it was evaluated with rigor (i.e., avoid a false positive conclusion). The challenge is to ensure that the use of the Red Flag concept remains within the context in which it was first considered by the Global Fund Board: **"a clear failure of AMFm design."**

- A red flag for every objective after 12-15 months of implementation: This approach does not take into account of the duration of the AMFm. It disregards the real life facts of how quickly innovations spread through population sub-groups. As such it is both mechanistic and inappropriate. Finally, it is internally inconsistent because it fails to relate the AMFm to the findings (on ACT access) of the recent Five-Year Evaluation of the Global Fund. The findings of the Five-Year evaluation concerning ACT illustrate multiple issues, to which the reader's attention is drawn:

  a) Time factor: There is a lag between financing disbursements and the use of ACTs being reported correctly in surveys.

  b) Comparators: Clearly, most of the countries have achieved poor results in ACT coverage (with the caveat of a possible lag as noted above). In choosing comparator countries, whether for the purpose of coverage or cost-effectiveness analysis, it is important for the analyst to avoid using as comparators the few exceptionally good performers since they do not reflect the median performance under the traditional business model that was evaluated.

  c) Limitation: In evaluations of complex interventions, even in a flagship study such as the Five-Year Evaluation, results are subject to caveats, context, judgment and reasonable nuance. It is wise for analysts and interpreters to avoid simplistic measures of "pass" or "fail." Had such an approach been taken when interpreting the Five-Year Evaluation, the performance on access to ACTs would have been a categorical "fail" and a failure of design. The logical consequence would have been for financiers to stop funding immediately the approaches that led to "perplexing and worrisome" findings. They have not done so.

- A Red Flag for every objective after 12-15 months of implementation including by the poor and other vulnerable populations: This approach does not take account of the duration of AMFm Phase 1. It disregards the real-life facts of how quickly innovations spread through population sub-groups. As such it is overly simplistic and inappropriate. Finally, it is internally inconsistent because it fails to relate the AMFm to the findings (on ACT access) of the recent Five-Year Evaluation of the Global Fund.

- Extension of the implementation period for much longer than 12-15 months, to observe how well co-paid ACTs will reach vulnerable populations in the medium- to long-term. This was rejected because it is not a design question but one of duration of execution. A few financiers have pledged contributions to the AMFm co-payment fund for ACTs. Pledges made as of mid-May 2009 are just about sufficient to cover estimated needs for the Board-approved duration of AMFm Phase 1. There are two points to consider:

    - If new financiers pledged *additional* funds to fully cover co-payments for an *extended* period of time under AMFm Phase 1, it might be appropriate to consider such an extension, depending on the timing and amount of such pledges. Absent firm pledges to cover an extension, AMFm Phase 1 will proceed and the evaluation will be conducted as presented in this Technical Framework.

    - Prolongation of Phase 1 means that other countries delay the start of AMFm on their territories, and will continue traditional approaches to the scaling up of ACT use, whose effects were found to be "perplexing and worrisome."

- ACT shortage: Interpretation of ACT shortage depends partly on the nature of the stock disruption. It could be a temporary disruption when a sudden increase in demand exceeds supply. Alternatively, it may be a sign of chronic system weakness (i.e., not peculiar to AMFm). Where such events occur, a situational analysis will clearly be required, with modifications and safeguards considered and built in.

7.4 Recognizing and Interpreting Red Flags

Table 15 lists red flags with indicators and triggers (i.e., the threshold for a red flag alert). Red flag triggers (i.e., thresholds that raise red flags) will be determined by the AMFm Ad Hoc Committee, with guidance from technical experts. They are matters of judgment, to be informed by the findings of the evaluation and the context. We will expect to see differences, with variations in progress in some areas or countries being due to lack of implementation or delays. What is made of the data and what is a reasonable time to scale-up are judgment issues. The evaluation will need to take into account progress in implementation in reaching a judgment on whether the results indicate satisfactory/promising impact of AMFm on increasing access.

Table 14: Red Flags and Threshold Triggers

AMFm element	Red Flag indicator	Threshold Triggers
ACT Availability	Proportion of outlets (all sectors) in rural /urban areas that have ACTs in stock at the time of survey visit	The Independent Evaluator will make a recommendation to the AMFm Ad Hoc Committee, based upon consultation with the countries, technical experts and a range of stakeholders as outlined in Section 8.2. *Considerations* will include the following: 1) Baseline projection (without AMFm): What is the local expectation of a plausible scenario if current approaches (traditional GFATM business line, no AMFm) continue for the next 24 months (i.e., in mid-2011)? 2) Projection with the AMFm: What is the local judgment of the scale, speed and effectiveness of supporting interventions during that period (assuming a sharp decrease in ACT prices under AMFm Phase 1)? 3) What is progress or lack of the same? Considering #1 and #2 above, what is the local expectation of worthwhile improvements over the scenario in #1 by the end of the implementation period for AMFm Phase 1? *They may set ranges instead of a single number. This will involve judgment (making sense from numbers based on context).*
	Proportion of the rural/urban population living in areas that have access to a full course of an adult/child treatment of ACT	
ACT Price	Median cost to patients of a full course of adult treatment of ACT in outlets in rural /urban outlets (i.e., compared to a full course of other anti-malarials)	
Market Share and Crowding Out	From Outlet Surveys: (a) Total volume of ACTs sold or distributed in the last week, as a proportion of the total volume of all anti-malarials sold or distributed in the last week, via outlets in rural / urban areas (b) Quantity of ACT procured by first line buyers ("unit" = boxes of ACTs by type and dosage) From Household Surveys: (c) Total reported volume of ACTs used by households with one or more inhabitants with fever in the past 2 weeks treated with ACTs, as a proportion of total volume of all antimalarials reported by the same households during the same period	

7.5 Frequency of Red Flag Monitoring

Red flags will be assessed at the end of the Phase 1 implementation period by comparing the baseline and end point data findings. Ideally, this formal point of analyses should be supported by *interval assessments (*i.e., to track and allow "real time" identification of serious failures). Given an implementation period of less than twelve months, and the level of effort required to plan and execute credible (market and utilization) surveys at the facility and household levels, it is not realistic to expect multiple, full-fledged surveys during a twelve month period.

- **Risk of drawing false conclusions:** The AMFm will be implemented in an environment where country-supporting interventions are nationally rolled out over time. Given the inevitable incremental nature of this process, a mini polling, or sampling of "red flag" indicators, could create false alarms, due to the "roll out" of the supporting interventions. The latter will influence not only end user awareness, knowledge and behavior but also that of providers too.

- **Resource & capacity limits:** Nation-wide outlet and household surveys at two time points (baseline and end point) within twelve months across eleven intervention and two to three comparison countries is possible but ambitious, given the involvement of experienced partners and building on current surveys. More regular monitoring surveys during roll out would not be feasible.

Nevertheless, AMFm Phase 1 countries are encouraged to undertake monitoring of ACT stock levels and prices in outlets[39] as part of M&E systems strengthening activities. This monitoring data could be used to track progress while paying strong heed to the risk of drawing false conclusions.

[39] *In terms of private sector outlets, this is limited to the registered private sector and excludes the informal private sector.*

8. RESPONSIBILITIES & MAJOR EVENTS DURING THE INDEPENDENT EVALUATION

Key Messages:

- The Global Fund Secretariat has the mandate to commission the independent evaluation of AMFm Phase 1. The Secretariat will seek independent technical counsel from an Expert Advisory Group (EAG) during this exercise. The EAG is not an oversight group.
- The AMFm Ad Hoc Committee has the mandate to oversee the independent evaluation of AMFm Phase 1. The Committee will seek inputs from the Technical Expert Reference Group during this exercise.
- There are seven major events in the conduct of the independent evaluation.

8.1 Commissioning and Oversight of the Independent Evaluation

The mandates for oversight, hosting, management and commissioning are as follows:

Commissioning

The Board has mandated the Global Fund Secretariat to host and manage AMFm Phase 1, and to commission an independent evaluation of AMFm Phase 1. With specific reference to the independent evaluation, the Board made the following decision at its 19th Meeting (May 2009):

> *"…Consistent with its previous decisions, the Board confirms that the Secretariat will continue to have responsibility for commissioning of the independent evaluation, under the oversight of the AMFm Ad Hoc Committee."*

As commissioner of the independent evaluation, the Global Fund Secretariat has convened an Expert Advisory Group (EAG) from which it has started to receive expert technical advice for its own use. The rationale is to assure timely and high quality advice from a body that is dedicated to the specific challenges of the AMFm, with a mix of skills that is customized for the specific purpose of the AMFm, and which has a finite lifespan. The EAG will have no role in the management or oversight of contractual processes for the independent evaluation, which will be the responsibility of the Global Fund Secretariat. The Expert Advisory Group is chaired by Barry Bloom (Professor and former Dean, Harvard School of Public Health).

Oversight

The Global Fund Board has mandated the AMFm Ad Hoc Committee to oversee the implementation and independent evaluation of AMFm Phase 1. With specific reference to the independent evaluation, the Board made the following decision at its 19th Meeting (May 2009):

> *"…The Board confirms that the Technical Evaluation Reference Group (TERG) will provide guidance with regard to the technical parameters of the design of the independent evaluation of the AMFm, under the oversight of the AMFm Ad Hoc Committee..."*

Pursuant to the decision of the Board, the Acting Chair of the AMFm Ad Hoc Committee has established communications with the Chair of the TERG.

8.2 Major Events in the Conduct of the Independent Evaluation

- Under the guidance of the independent evaluation contractor to be selected via competitive tender, **standardization of indicators and survey methods** across the organizations who are separately contracted by the Global Fund Secretariat to implement the household and outlet surveys [i.e., data collection organizations with established infrastructure, networks and proven track records in conducting ACT market surveys in target countries]

- **Baseline data collection**[40]

- **In-country monitoring** of supporting interventions and operational research

- **End point data collection** [i.e., by same survey organizations that conducted the baseline]

- **Analysis and preparation of draft data analysis report** on AMFm objectives, methods and results by the Independent Evaluator:
  - Standardization of indicators, survey methods and country datasets (for baseline and end-point data collection)
  - Data quality checks
  - Analysis
  - Preparation of Draft Data Analysis Report on Results [Quantitative and qualitative results -- no interpretation and no recommendations *at this stage*]

- **Consultative forum for stakeholders** convened and managed by the Independent Evaluator:
  - Presentation of objectives, methods and context
  - Presentation of draft results
  - Discussion of draft results with reference to objectives, methods and context

  Note: The added value of this forum is to ensure that the independent evaluation is informed by the body of knowledge from key institutions, thought leaders and practitioners whose expertise and perspectives are relevant to the subject matter. However, as this forum is consultative and not an executive forum, the Independent Evaluator will ultimately decide which suggested considerations and comments are worthy of being taken into account when interpreting findings in the final analysis. The Independent Evaluator will prepare a full report of the forum which will be made available in the public domain and distributed to all forum participants.

- **Preparation of full draft report** by the Independent Evaluator on objectives, methods, results, interpretation (implications for policy and practice), conclusions and recommendations (with the report of the stakeholder forum in annex)

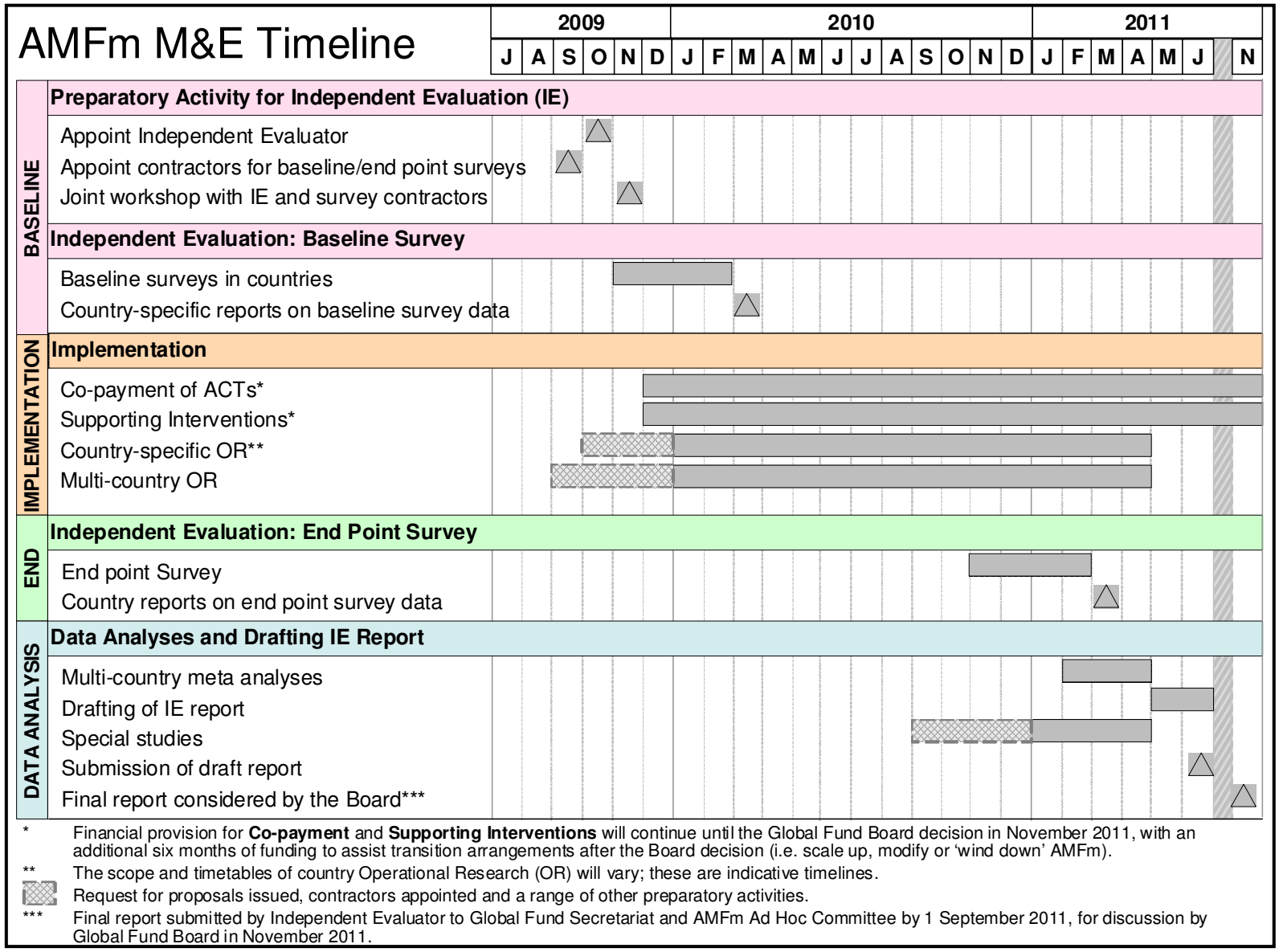
- **AMFm Ad Hoc Committee presents the independent evaluation report to the Global Fund Board**

[40] *Prior to baseline data collection, the independent evaluation contractor will convene a meeting with all data collection organizations under contract to implement the surveys in order to standardize and harmonize data collection processes.*

9. OVERVIEW OF M&E TIMELINE

This chart (Figure 5) presents an overview of major M&E activities by time across different components of the Framework.

Figure 5: Overview of M&E Timeline



Annex I:

AMFm OBJECTIVES, EVALUATION QUESTIONS & ILLUSTRATIVE INDICATORS

This table shows how AMFm objectives, evaluation questions and some illustrative indicators, at the output and outcome level, map onto each other.

AMFm objectives	Key evaluation questions	Illustrative indicators[1]	
		Output-level	Outcome-level
AMFm Obj. 1: Increase availability of quality assured ACTs in outlets across public, private for-profit and not-for-profit sectors	• Has the AMFm helped increase the availability of quality assured ACTs to patients in rural /urban areas?	• Proportion of outlets in rural/urban areas that have quality assured ACTs in stock at time of survey visit • No. and % of outlets in rural/urban areas, with no reported stock-outs of nationally recommended anti-malarial drugs lasting more than 1 week at any time during the past 1 month	• Proportion of children [by age band] with fever in the past two weeks who received ACTs • Proportion of children [by age band] with fever in the past two weeks who received ACTs within 24 hours of fever onset • Proportion of households in poor areas with one or more inhabitants with fever in the past 2 weeks treated with ACTs
AMFm Obj. 2: Increase affordability of quality assured ACTs to patients in outlets across public, private for-profit and not-for-profit sectors	• Has the cost of quality assured ACTs to patients been reduced at outlets in rural/urban areas, to a price comparable to the target price of the most popular anti-malarials?	• Median cost to patients of a full course of treatment (adult/child) with quality assured ACTs in rural/urban outlets • Median cost to patients of a full course of [AMT/ other anti-malarial] (adult/child) in rural/urban outlets • Cumulative % mark-up between retail median price of a full course of treatment with quality assured ACTs (adults) and wholesaler median price	
AMFm Obj. 3: Increase use of quality assured ACTs, including by vulnerable groups	• Has the AMFm mechanism helped increase use of quality assured ACTs, including among vulnerable groups, such as poor people, children and rural dwellers?	• Use of ACTs is measured at the outcome level.	
AMFm Obj. 4: Increase market share of quality assured ACTs in outlets across public, private for-profit and not-for-profit sectors (i.e. WHO pre-qualified ACTs relative to AMTs, SP and CQ)	• Has the AMFm helped increase the market share of quality assured ACTs, as a proportion of all anti-malarial treatments, in the public, private for- and not-for-profit sectors?	• Total volume of quality assured ACTs sold or distributed in the last week as a proportion of the total volume of all anti-malarials sold or distributed in the last week via outlets across sectors in rural/urban areas	

1 **Indicators in this figure appear in a summary fashion.**

Annex II:

RESPONSES TO ADDITIONAL COMMENTS RECEIVED DURING THE DEVELOPMENT & REVIEW OF THE M&E TECHNICAL FRAMEWORK

The AMFm (Phase I) Monitoring & Evaluation Technical Framework incorporates feedback received from a range of stakeholders and advisors, including the following: AMFm Ad Hoc Committee; AMFm Phase 1 country officials; Expert Advisory Group to the Global Fund Secretariat; Global Fund Technical Evaluation Reference Group; and selected technical partners. The comments that follow were extracted from feedback correspondence. Many of these considerations are reflected in the body of the document, but they are presented here for ease of reference because of their importance to discussions about the Technical Framework.

❖ ***Comment 1***

Attribution of success: The current evaluation design does not control for one of the key components of the AMFm platform: the supporting interventions. By relying on routine grant performance reporting for measurement of the supporting interventions, the evaluation as designed will not allow for a precise measurement of these interventions. As such, in the final analysis, this design flaw may not allow the evaluators to adjust for differences in supporting interventions and as a result may attribute biased effect to the co-financing of ACTs. In other words, under the current design, an observed increased use of ACT at the end of the evaluation may in fact be the effect of successful supporting interventions and may not be related to an ACT price reduction.

Response: The Global Fund Board approved AMFm as a combination of price reductions and supporting interventions, not as optional elements. Therefore, the primary question of interest is the extent to which that combination works. Nevertheless, the following notes address the question of attribution:

- The Independent Evaluation of AMFm Phase 1 is concerned with the questions specified in Chapter 6 and methods for answering those questions. It is NOT concerned with a "precise measurement of the supporting interventions" as an end in itself.
- To know the separate effects of price reductions and supporting interventions, it would be necessary to divide countries into the following groups: (i) no AMFm, only business as usual; (ii) business as usual plus price reductions only; (iii) business as usual plus supporting interventions only; (iv) business as usual plus price reductions plus supporting interventions. Any introduction of co-paid ACTs without price reductions would have met stiff resistance and charges of unethical practice. Therefore, the design of the independent evaluation is a sensible approach that fits the prior decision of the Global Fund Board to combine price reductions with supporting interventions.
- From basic economics, it is known that price reductions tend to result in increased demand, *ceteris paribus*. The use of comparator countries will make it possible to draw comparisons between the AMFm and non-AMFm countries, with caveats that apply to quasi-experimental studies. It should be noted that some elements of supporting interventions were being implemented before the AMFm. *If these alone were capable of resulting in massive increase in ACT coverage within a 12-month period, such increases would have been detected by the Five-Year Evaluation*.

- If one attributed an observed increase in ACT to the effect of supporting interventions and not a price reduction, a logical conclusion could be that development assistance in general should no longer seek to reduce the prices of ACTs to end-users (but let the medicines be delivered at prices determined by the market), and concentrate on supporting interventions only. Multilateral and bilateral donors would stop those elements of their operations that seek to deliver subsidized ACTs in any form, concentrate on supporting interventions only, and perhaps introduce whatever user fees the market can bear (since price reductions would not matter in that scenario).

❖ ***Comment 2***

Duration of the evaluation: The short timeframe for the AMFm evaluation may not allow enough time for the supporting interventions to take root and influence consumer behavior. Thus, the results may not yet show the benefit of the improved availability, access to and affordability of ACT.

Response: This is noted and addressed in the text of Chapter 7.

❖ ***Comment 3***

Comparison countries: The choice of countries to be included in control groups should be made mainly on the basis of comparable treatment seeking behavior in addition to a comparable malaria burden, since this is directly related to the main outcome being evaluated. In addition, the comparison countries should not be bordering with study countries to prevent leaking of low priced ACT.

Response: The point is noted and will be taken into account, to the extent that is feasible in terms of logistics, geographic realities and incremental costs.

❖ ***Comment 4***

AMFm goals: This evaluation considers the interim indicators of affordability, availability and use of ACT. It does not attempt to measure success against the main goals of AMFm which are to save more lives by making ACTs more available and affordable; and to slow down resistance by reducing the use of artemisinin-based monotherapies, and increasing the use of ACTs.[41] Any observed improvements in these interim indicators would not necessarily imply the achievement of AMFm goals. These are necessary but not sufficient conditions to ensure success. Many other factors can affect the success of the initiative, such as full treatment of actual malaria cases, competing diseases, reduced awareness of prevention, etc. Indicators closer to AMFm objectives (e.g., trends in malaria cases, admission to clinic for fever, under-5 child mortality) should also be monitored for surveillance purposes, even beyond the time-frame of Phase 1.

Response: AMFm Phase 1 is essentially a "proof of concept" on a large scale. As shown in Figure 1 (AMFm Phase 1: Results Framework), the objective of Phase 1 is not to demonstrate attributable declines in mortality. It is conceptually wrong to describe "admission to clinic for fever" as "closer to AMFm objectives."

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[41] *Affordable Medicines Facility – Malaria (Phase 1) Monitoring & Evaluation Technical Framework (Draft 2, 27 May 2009).*

- ***Comment 5***

  Cost-effectiveness: As a financing platform, the cost effectiveness of AMFm should be analyzed and clearly described. This is of special relevance when we consider the arguments for dedicating similar levels of investment to already-cost-effective supporting interventions and prevention activities.

  Response: The questions of cost-effectiveness and comparisons are noted in Section 6.11. The reader's attention is drawn to Box 6. In addition, it should be noted that based on the findings of the Five-Year Evaluation, there is no evidence to conclude that the traditional business line of scaling up access to ACTs was either effective or cost-effective.

- ***Comment 6***

  Institutional analysis: An institutional analysis related to the scalability of AMFm will be important to inform the Board decision as to whether to develop this new business line in the future and this should be well described in the evaluation.

  Response: The point is noted.

- ***Comment 7***

  Market effects: The impact of the AMFm on the global and national ACT markets should be further investigated during the evaluation since the initiative may have socio-economic implications beyond health (e.g., reducing outlets for ACT promotion, lower income for these outlets, and disruption of national markets).

  Response: The observation above includes speculative assertions that are difficult to respond to. For example, if a financing platform seeks to expand points of service from public sector and some NGOs to a combination of the public sector, all willing and able NGOs, and the private sector, it is unlikely that such a platform is "reducing outlets for ACT promotion."

- ***Comment 8***

  Whether the medicines *reach those not currently reached by other providers*, which is the whole purpose of AMFm. This means that the evaluation should look at how well AMFm reached remote and rural area where NO PUBLIC service is available. Competing with currently available public or NGOs services - even if price is down and uptake is high - is not a success because services already exist.

  Response: The study design provides for household surveys that will include remote and rural areas. For clarity, the AMFm is a financing platform intended to facilitate access for all, with attention to the currently underserved. Based on the Five-Year Evaluation, the effects of what is being done by current services are not clear.

- ***Comment 9***

  Impact on the use of current services: whether there is increased uptake in the new service but decreased in existing services, i.e., the net use is the same rather than more use ON TOP of current service.

  Response: For each country, the pre-post comparisons will answer this question, both in aggregate and for sub-sectors.

- ***Comment set 10***

  Treating malaria and not any fever: Number of fevers treated is not sufficient. It is important to differentiate which fever is treated by ACT. We cannot consider success even if ACT is increased by 90% but 90% of these is pneumonia. Apart from wasting precious resources (which we may have to swallow), it is a big danger for children that we cannot accept.

  On Scope and Diagnostics: The purpose of the evaluation is not to be yet another evaluation of all the weaknesses of the existing public and private (profit, non-profit and informal) health systems and how they affect the access and use of current antimalarials. The AMFm is all about using existing antimalarial drug channels and presumptive malaria patient contacts and allowing quality ACTs to replace the current inappropriate drugs: the less effective CQ, or those who threaten the effectiveness of ACTs: the mono-artemisinins (price fell steeply since 2007) or underdosed counterfeit ACTs, some containing dangerous substances.

  Replacing those inappropriate drugs by ACTs in non-malaria fevers can never worsen the outcome. Fevers due to benign viruses, pneumonia or typhoid are not better off with CQ, AQ, mono-artemisinins or underdosed ACTs. In Plasmodium carriers, ACTs are always a better option than mono-artemisinins or substandard ACTs with regard to resistance, whatever the compliance is, and whether there is fever or not, and whether the fever is due or not to the Plasmodia.

  What should the basis for evaluating the AMFm? The AMFm should be evaluated versus the national treatment guidelines: i.e., if, for instance, the guidelines say that antimalarials should be provided presumptively for any type of febrile illness, then the AMFm needs to be measured against that particular metric, not against that of non-malarial fevers.

  Response: These comments are noted. Countries were encouraged to include improved diagnostics as a supporting intervention or operational research topic. The AMFm will be implemented within national treatment guidelines and the evaluation will take those into account.

- ***Comment 11***

  Supporting intervention: It is important to figure out quantitative and qualitative indicators for it. For example, 10 training sessions is one thing but how long, for whom, content, and above all whether what was said is actually done in the shops, is more important. Training is not enough. Supervision is crucial.

  Response: Supervision is included under supporting interventions in the AMFm application forms. Country-specific operational research provides for studies of the

quality of supporting interventions, IEC/BCC approaches and "the appropriate use of ACTs and compliance with the full course of treatment" (see Section 5.1).

- ***Comment 12***

Affordability: Also add what coping strategy do people use to afford the price. There is a huge difference between willingness to pay and ability. There are tons of studies on how poor people pay heavy price in terms of reducing food intake, taking girls from school, etc., in order to afford even a few cents for treatment. What is little money in the eyes of the outside world could be prohibiting price for people who have to pay many times/year.

Response: Operational research studies are more suitable to examine this particular topic, perhaps as particularly of studies on reaching the poor with ACTs. In the private sector market, a household that cannot afford to pay 20-50 cents for co-paid ACTs (as envisaged under the AMFm) would be considerably worse off in the non-AMFm scenario (paying up to 20 times that amount).

- ***Comment 13***

Time plan: It is absolutely essential that we have enough data from the independent evaluation to provide sufficient evidence for the Global Fund board to make a decision. Therefore, we need to have reasonable implementation time, and the timeline should be revised accordingly.

Response: This opinion is noted. The reader's attention is drawn to the fact that the Technical Framework is designed within the timeline mandated by a decision of the Board of the Global Fund. Chapter 7 of this Technical Framework provides the technical and operational basis for the approach taken within that timeline.

- ***Comment 14***

The language on "design" and "implementation" should be deleted.

Response: The recommendation is noted. The language is retained because there is a fundamental difference between a failure of design and a failure of implementation, and the latter may be related to insufficient time for implementation to achieve desired results. The report of the Five-Year Evaluation, which is cited in Box 2, acknowledges the time factor. Otherwise, a logical conclusion would be that both the design and implementation of the financing platform and programs assessed by the Five-Year Evaluation had failed.

- ***Comment 15***

Evaluating access and use by the poor: Household-level data is a key source of information to evaluate whether the AMFm has increased use by poor and vulnerable populations.

Response: The reader is referred to Table 9 (Data collection methods, frequency and responsibilities).

- ***Comment set 16***

On proper Use of ACTs

Comment 16.1: In collecting data on the use of ACTs, there are two vital elements of use that the evaluation should assess: 1) the degree to which the AMFm is promoting the rational use of ACTs in responding to any type of febrile illness, and 2) the extent to which this usage meets standards of treatment compliance. At the moment, there are no evaluation indicators that seek to determine whether ACTs are properly used. An inherent risk in the AMFm model is that a dramatic increase in the use of ACTs with incomplete or improper courses of treatment could, of course, actually accelerate the development of resistance to ACTs. The increased availability of ACTs through untrained shopkeepers selling to poor and vulnerable populations accentuates this risk. Since a primary purpose of the AMFm is to help delay the onset of resistance to ACTs, the evaluation should seek to assess the extent to which ACTs are being use properly.

Comment 16.2: The AMFm should be evaluated versus the national treatment guidelines: i.e., if, for instance, the guidelines say that antimalarials should be provided presumptively for any type of febrile illness, then the AMFm needs to be measured against that particular metric, not against that of non-malarial fevers.

Comment 16.3: The AMFm needs to be evaluated against counterfactuals, not against some utopian state. For instance, if ACTs are more broadly used but compliance is 60%, that will still be a better outcome from the resistance prevention perspective than a counterfactual scenario where monotherapy artemisinin is broadly used & compliance is 60%. For the evaluation to be meaningful, we will need to compare compliance (and for that matter coverage among the poor) with a counterfactual (e.g., the public sector): by failing to do so, we assume, heroically, that the public sector achieves very high compliance and provides access to the neediest.

Comment 16.4: We are concerned that monitoring the rationale use of ACTs, a critical element for success has not been adequately reflected in the document. The M&E framework as it stands, includes intermediate indicators that measure availability of ACTs and price. It lacks a robust plan to assess use. In addition, indicators measuring "use" are referred to within recommended operational research or supporting interventions instead of being part of the core list of indicators. We recommend that the pilot program measure actual increase in use of ACTs as well as include indicators that monitor patient compliance.

Response: These comments are noted. The Framework includes explicit measures of use (see Tables 6 and 8). The AMFm will be evaluated against real-life counterfactuals.

❖ ***Comment set 17***

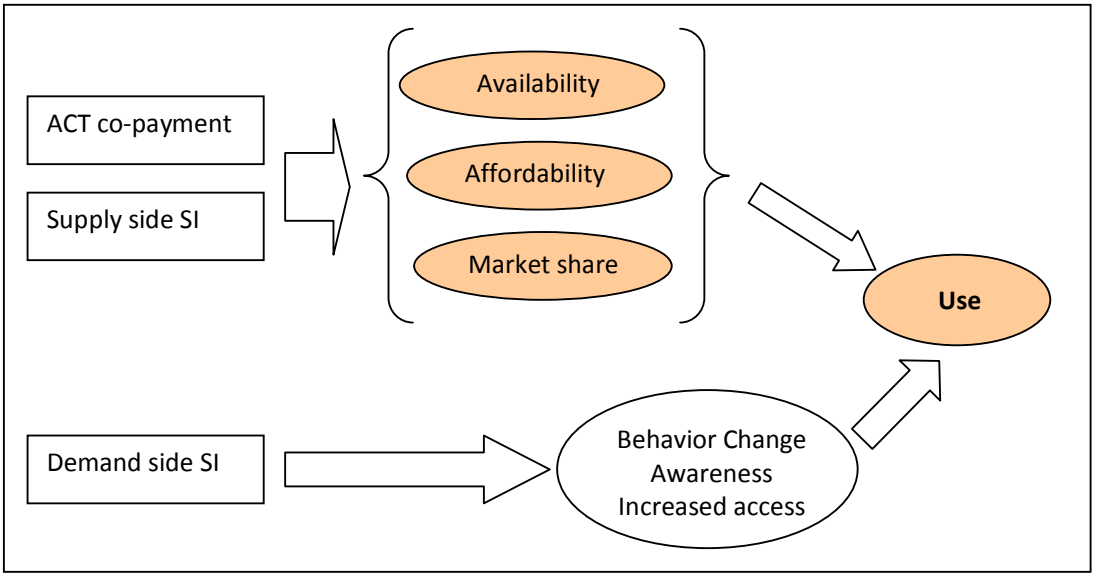
Comments on the design

Comment 17.1: The intervention under evaluation is the AMFm platform, which includes both the ACT price reduction initiative and AMFm supporting interventions. Supporting interventions can be classified according to two categories:

(a) Interventions affecting the supply side (i.e., training of providers, drug monitoring, etc.); and

(b) Interventions affecting the demand side (i.e., public awareness, outreach activities, etc.).

AMFm objectives include availability, affordability, market share and use (shown in orange in the below graphic). Affordability, availability and market share are outputs of the combination of AMFm ACT co-payment and the AMFm supporting interventions (SI) affecting the supply side. However, the use of ACT is an outcome based on the combination of both these three outputs and the effects of demand side interventions (shown below in white).



The proposed methodology, using "reporting requirements similar to Global Fund routine country grant practice" for supporting interventions (p.3) will likely not allow the evaluators to capture the effects of demand side supporting interventions on behavior change, awareness and increased access, and thus will not allow the evaluation to show the added benefit of AMFm on the use of ACT. The effect of the demand side supporting interventions could, however, be assessed in the household survey in both control countries and AMFm countries in order to reduce potential bias.

What is not fully clear in the framework, is whether interventions affecting the demand side are considered to be part of the AMFm platform or not. Indeed, the effect of the demand side interventions is currently not considered a key component of the evaluation and there are no red flags covering these interventions. In addition, the framework document seems to suggest that it might be difficult to measure increase in use of ACT ("expectations about population-wide shifts in ACT use needs to be realistic" p33). As such, the evaluation needs to balance the need

for quick results against the risk of not having population-based measures of success. It is clearly crucial to determine a realistic duration for this pilot phase.

Comment 17.2: It is important to keep in mind at all times that AMFm has two components: the buyer subsidy and the supporting interventions. For this reason, the combined or total effect of the two components is the main concern of the evaluation and although the decomposition of the total effect into the subsidy and SI effects are important, certainly it is secondary. It is like the total effect of a price change on quantity demanded in elementary economics. Decomposing the total effect into income and substitution effects are important but will generally be secondary to the significance of the total effect.

Responses:

The comments are noted. Specifically:

- Timeline: The timeline is based on Global Fund Board decisions in effect as of July 2009. The timeline can be amended if subsequent Global Fund Board decisions make such amendments necessary.

- Demand generation is part of supporting interventions. Measures of market share and use will reflect the combined effects of several aspects of the AMFm, including but not limited to demand generation.

- Both the household and outlet surveys will provide information on factors that influence demand. For example, information campaigns aimed at households influence demand. Information provided to service providers in pharmacies and drug shops can also influence demand because these workers influence choices made by patients who come to the pharmacies and shops; this was the case in the pilot experiment conducted in Tanzania by the Clinton Foundation, and is consistent with the literature on supplier-induced demand.

❖ ***Comment 18***

Attribution of increased ACT coverage
As explained in the TERG Summary Paper on Study Area 3 of the Five-Year Evaluation, because changes in ACT policy occurred so recently in many countries, it was not possible at the time of the evaluation (2008) to assess the effects of existing supporting interventions on ACT coverage. As stated in the Final report on SA3 (and as quoted in the AMFm evaluation framework on p.9) "new surveys should clearly show large increases in ACT coverage for 2008-2009." This obviously highlights a challenge for the AMFm independent evaluators since these increases in coverage could in fact be wrongly attributed to AMFm.

Response: The baseline survey, which is scheduled for the end of 2009/start of 2010, will show the state of affairs *at the start* of the AMFm. Comparisons between the baseline and end point surveys, which will take into account the findings in comparator countries, will make it possible to assess what increments may or may not be due to the AMFm. The selection criteria for Independent Evaluator will include very strong skills and track records of performance in study design and analysis, including a capacity to detect and mitigate risks of wrongful attributions of cause and effect.

❖ *Comment 19*

Comparator countries
The evaluation framework document states that "countries whose AMFm applications are not approved by Global Fund's Technical Review Panel will be considered for selection as comparator countries" (p.29). Including these countries as comparators may introduce a design bias as any countries who don't meet criteria for inclusion are likely to have been rejected due to poor expected performance. In addition, since the level of technical assistance (TA) provided to countries will impact the effectiveness of the interventions, TERG strongly recommends that the evaluation include a close monitoring of the TA provided to both AMFm and comparator countries.

Response:

- Clearly, these comparator countries are not matched controls. Because they are among those selected on the basis of relevant criteria to apply to the AMFm, all applicants (regardless of the eventual verdict on their applications) were pre-judged as among the most likely to succeed. Therefore, even those applications are not successful are plausibly closer to successful applicants than those who were not invited to apply. Readers are referred to the literature on quasi-experimental designs for more information on methods (see, for example, Campbell and Stanley, 1963; Robson, 1993; Valadez and Bamberger, 1994).
- TA is part of the intervention package of AMFm Phase 1, particularly the supporting interventions. Therefore, if the AMFm succeeds partly because of TA, that would be a good thing because it would have demonstrated effectively deployment of TA.

❖ *Comment 20*

Direct Comparisons between AMFm and other (non-Global Fund) Financing Platforms
There is a particular concern with regard to the proposed plan to compare the AMFm's results to the U.S. President's Malaria Initiative (PMI). This section seems to misunderstand the purpose and methods of PMI. One of the criteria for inclusion as a focus country within PMI is that the country has already received significant financing from the Global Fund, and PMI seeks always to work within national strategies and plans, performing a "gap-filling" role, and providing technical assistance. So it would generally be difficult to characterize any PMI program as a "non-Global Fund" financing platform, or to distinguish between their activities.

There could be value in comparing the effort to increase access to ACTs via different models of treatment expansion, including through other (non-"factory gate") subsidies or through community health workers, regardless of the source of financing.

Response: Given this information, (a) PMI will not be included among initiatives for direct comparisons with the AMFm, (b) no data from any separate evaluation of PMI will be admissible for comparison purposes, especially as it is difficult to distinguish between activities financed by PMI and those financed by the Global Fund.

- ***Comment 21***

Cost-effectiveness considerations
Given the resource constraints for health, the main objective of the Global Fund should be to maximize impact through promoting cost-effective interventions. However, based on the description in part 6.11.3 of the framework (p39), the likelihood of being able to complete this exercise may be quite low if "comparators must be on *at least the same scale* and present at least the same contextual diversity as AMFm Phase 1" and if the analysis is only performed "to the extent that data are available or can be collected within budget."

Response: It would be easier to find a small-scale comparator. However, that would not be appropriate for the relevant policy discussions because small-scale projects do not include the complexity and diversity of scaling up, which AMFm Phase 1 would include. Therefore, their cost structures do not necessarily reflect the cost structures of large-scale efforts. The Global Fund Board wanted a large-scale Phase 1 of the AMFm to inform its decision. Otherwise, the pilot ACT subsidy experiment in Tanzania, which was commissioned by the Clinton Foundation and illustrated the potential of the AMFm, might have sufficed for a decision to go to a global roll out of the AMFm. That pilot experiment in Tanzania, not a large-scale Phase 1, is perhaps a reasonable basis for comparison with small-scale, non-AMFm initiatives. In order for comparators to be meaningful, they should be on a similar scale.