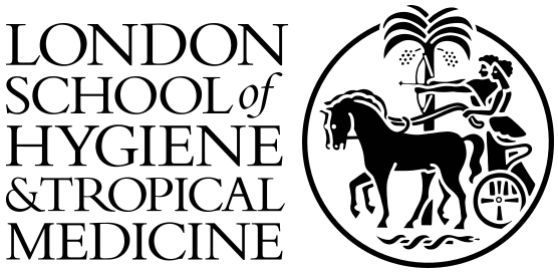

# Implications of ACT Reprogramming on Performance-based Funding of the Global Fund

A thesis submitted to the Faculty of Science of the University of

London in fulfilment of the requirement

for the degree of

Doctorate in Public Health


**By**

**Sandii Lwin**

**Faculty of Infectious and Tropical Diseases**
**London School of Hygiene and Tropical Medicine**

**August 2022**

**No funding was received for this research study**

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## LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ACT | Artemisinin-based Combination Therapy |
| ADR | Adverse Drug Reaction |
| AIDS | Acquired Immunodeficiency Syndrome |
| AMDS | AIDS Medicines and Diagnostics Service |
| AQ | Amodiaquine |
| ARV | Anti-retroviral (for AIDS) |
| CCM | Country Coordinating Mechanism |
| CDC | Centre for Disease Control |
| CI | Confidence Intervals |
| CIDA | Canadian International Development Agency |
| CMH | Commission for Macroeconomic and Health |
| CQ | Chloroquine |
| CP | Condition Precedent |
| DHS | Demographic and Health Surveys |
| DOTS | Directly Observed Therapy-Short Course |
| DPT | Diphtheria, Tetanus and Poliomyelitis vaccines |
| DQA | Data Quality Audit |
| DRC | Democratic Republic of Congo |
| EPI | Expanded Programme on Immunisation |
| FAO | Food and Agriculture Organisation of the United Nations |
| FAR | Federal Acquisition Rules and Regulations |
| FARAs | Fixed Amounts Reimbursable Agreements |
| FPMs | Fund Portfolio Managers |
| GAIN | Global Alliance in Nutrition |
| GAO | Government Accountability Office |
| GAP | Good Agricultural Practice |
| GAVI | Global Alliance for Vaccines and Immunisation |
| GDF | Global Drug Facility |
| GEF | Global Environment Facility |
| GFATM | Global Fund to fight AIDS, Tuberculosis and Malaria |
| GHI | Global Health Initiative |
| GIPRA | Government Performance and Results Act |
| GLC | Green Light Committee |

| | |
|---|---|
| GMP | Good Manufacturing Practice |
| GPR | Grant Performance Report |
| GTT | Global Task Team (on HIV/AIDS) |
| HIV/AIDS | Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome |
| HSS | Health Systems Service |
| IAPSO | Interagency Procurement Services Office |
| ICC | Interagency Coordinating Committee |
| IDA | International Dispensary Association |
| IEC | Information, Education and Communication |
| IOM | Institute of Medicine |
| IMF | International Monetary Fund |
| IPT | Intermittent Presumptive Treatment |
| IPTT | Initiative for Pharmaceutical Technology |
| IRC | Independent Review Committee |
| IRS | Insecticide Residual Spraying |
| ITNs | Insecticide Treated Nets |
| KPC | Kunming Pharmaceuticals Corporation |
| LFA | Local Fund Agent |
| LOI | Letter of Intent |
| LLITNs | Long Lasting Insecticide Treated Nets |
| MAP | Multi-country HIV/AIDS Programme of the World Bank |
| MDG | Millennium Development Goals |
| M & E | Monitoring and Evaluation |
| MMSS | Malaria Medicines and Supply Services |
| MIT | Massachusetts Institute of Technology |
| MMV | Medicines for Malaria Venture |
| MSF | Mèdicins Sans Frontières |
| MSH | Management Sciences for Health |
| NEPAD | New Partnership for Africa's Development |
| NGO | Non-governmental Organisation |
| OAU | Organisation of African Unity |
| OECD | Organisation for Economic Co-operation and Development |
| OMB | Office of Management and Budget |
| P. | Plasmodium |
| PEPFAR | President's Emergency Plan for AIDS Relief |

| | |
|---|---|
| PMI | President's Malaria Initiative |
| PMU | Project Management Unit |
| PR | Principal Recipient |
| PQRM | Price and Quality Reporting Mechanism |
| PPP | Private Public Partnership |
| PSM | Procurement and Supply Management |
| RBM | Roll Back Malaria |
| RCC | Rolling Continuation Channel |
| SEARO | Southeast Asia Regional Office (WHO) |
| SP | Sulfadoxine-pyrimethamine |
| SWAps | Sector Wide Approaches |
| TA | Technical Assistance |
| TB | Tuberculosis |
| TL | Team Leader |
| TERG | Technical Evaluation and Reference Group |
| TRP | Technical Review Panel |
| UK | United Kingdom |
| US | United States |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNDAF | United Nations Development Assistant Framework |
| UNDP | United Nations Development Programme |
| UNGA | United Nations General Assembly |
| UNGASS | United Nations General Assembly Special Session on HIV/AIDS |
| UNICEF | United Nations Children's Fund |
| UNIDO | United Nations Industrial Development Organisation |
| USAID | United States Agency for International Development |
| USD | United States Dollar |
| VF | Verification Factor |
| VPP | Voluntary Pooled Procurement |
| WFP | United Nations World Food Programme |
| WHO | World Health Organisation |
| WPRO | Western Pacific Regional Office (WHO) |

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## GLOSSARY

**Country Coordinating Mechanism (CCM):** The CCM is a country level partnership that coordinate proposals to the Global Fund; select the Principal Recipient (PR); monitor the implementation of activities under approved programmes, including approving significant changes in implementation plans as necessary; evaluate the performance of a programme, submit a request for continued funding prior to the end of the two years of the initially approved funding from the Global Fund; ensure links and consistency between Global Fund and other health and development assistance programmes in support of national priorities.

**Global Fund Board:** The Global Fund's 23-person international Board includes representatives of donor and recipient governments, nongovernmental organisations, the private sector (including businesses and foundations) and affected communities. UN agencies have three non-voting seats at meetings on the Global Fund Board of Directors. These are held by the World Bank (Global Fund's Trustee), WHO and the UNAIDS Secretariat (on behalf of other cosponsoring agencies).

**Global Fund Secretariat:** The Global Fund's staff is responsible for day-to-day operations based in Geneva, Switzerland. The Secretariat is divided into operational units (such as procurement, finance, monitoring and evaluation, legal) and into eight regional "clusters" (Southern Africa, East Africa, West and Central Africa, Middle East and North Africa, South Asia, East Asia and Pacific, Latin American and the Caribbean, and Eastern Europe and Central Asia), which manage the Global Fund grants. Each cluster is comprised of a Team Leader and several Fund Portfolio Managers (FPMs), and is delegated responsibility for the management of grants in specific countries.

**Local Fund Agent (LFA)**: Independent organisations hired by the Secretariat to assess the PR's capacity to administer funds and provide ongoing oversight and verification of reported data on financial and programmatic progress.

**Performance-Based Funding (PBF):** Performance based funding is the process of awarding grant funds to PRs based upon their satisfactory completion of milestones detailed in the grant.

**Phase 1:** Initial two-year period of the grant.

**Phase 2:** The remaining proposal period (years 3-5) post initial two-year grant period.

**Principal Recipient (PR):** A local entity nominated by the CCM and confirmed by the Global Fund to be legally responsible for grant proceeds and implementation in a recipient country. There may be multiple public and/or private PRs in a country.

**Reprogramming:** Reprogramming is a methodology that is utilised by Global Fund as a flexible performance-based funding instrument, to adjust defined grant programmes to accommodate changes in global markets as well as in-country changes (socio, economic, political), and related environmental issues. Reprogramming can be best described as a methodology to alter an existing grant to accommodate events and situations that can affect the satisfactory performance and implementation of the grant by a Principal Recipient. Specifically, it allows PRs to make adjustments to their workplans in order to align with programme realities contained within the grant agreement.

**Significant or material reprogramming:** there are two levels of reprogramming recognized by the Global Fund, ”routine” reprogramming and “significant or material reprogramming”; where the former supports changes in the rules of the grant and may encompass the work plan, budget and performance indicators. The latter, considers changes that are so substantive that they question the original intent of the approved proposal by the Technical Review Panel (TRP). In such circumstances, the revised proposals are submitted to the TRP for reconsideration.

**Sub-Recipient (SR):** An implementing partner that receives disbursements from the Principal Recipient.

**Technical Review Panel (TRP)**: An independent panel of disease-specific and cross-cutting health and development experts that provides a rigorous review of the technical merit of applications.

## ACKNOWLEDGEMENT

I am indebted to my supervisor, Dr Jo Lines for his immense understanding, guidance, critical input and his unwavering support throughout these years. My gratitude goes to my advisory panel members, Dr Sylvia Meek, Dr Ruairi Brugha, for their mentorship, valuable input and advice on the thesis topic. I am also grateful to Dr Vinand Nantulya, Mr Elhadj Sy, Dr Susan Scott for being a source of inspiration, and for their valuable advice; and to Professor Sir Richard Feachem for allowing me to conduct this important study.

I would also like to thank my good friends and colleagues Mr Carl Manlan for his assistance, critical input and continued support over the years, Mr Roberto Garcia, Ms Karmen Bennett, and Global Fund Portfolio Managers for their contribution.

Many thanks go to my close colleagues from Roll Back Malaria Partnership including members of the Secretariat, East African Regional Network, West African Regional Network, Melanie Renshaw from UNICEF and Malaria programme managers.

The thesis is dedicated to my friends and family for their loving support and for their belief in me.

## DECLARATION BY AUTHOR OF THE DISSERTATION

I confirm that this dissertation is the result of my own work and that the idea for this thesis was conceived by me. I received supervision from Dr Jo Lines, Dr Sylvia Meek, and Dr Ruairi Brugha throughout the period of my doctoral research. While my supervisors supported me in developing the material that contributed to the paper, the thesis itself is my original work. I acknowledge the role that others have played throughout the period of my degree, however all errors and omissions in this document are my own.

**IMPLICATIONS OF ACT REPROGRAMMING ON PERFORMANCE-BASED FUNDING OF THE GLOBAL FUND**

## ABSTRACT

**Background:** The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), created in 2002 with a performance-based funding model, grounded in country ownership and based on achievement of performance indicators. In 2004, the Global Fund faced international pressure calling for a shift to a more effective treatment regime - artemisinin Combination Therapy (ACT) for malaria grants and to accelerate efforts at country level. The Global Fund responded by taking immediate action requesting countries to switch to the new drug treatment regime on short notice. The study examines special performance-based funding tools used by the Global Fund and the impact on countries requested to reprogramme. This tension due to the technical shift in drug treatment and the processes undertaken during this period is part of this research and its findings through the lens of learning organisations.

**Methods:** Case study research methodology was applied for this research involving both quantitative and qualitative methods including participant observation and narration.

**Findings:** The study provided insights into unintended effects of Global Health Initiatives (GHIs) and various intervention complexities in malaria programmes within the health sector. Several factors significantly impacted ACT reprogramming at the Global level, within the Global Fund Secretariat, and at the country level. Despite the availability of special PBF instruments, countries were unable to meet the performance targets due to time taken to change national drug policies to implement these activities compounded by other factors including a global supply shortage with limited supplier selection. These externally driven events led to countries being penalized from securing future malaria grant funding by the lack of programmatic progress achieved during the period of 2004-2006. There was an 80% failure rate for all malaria proposals submitted by the countries earmarked for reprogramming for two successive rounds of funding.

**Conclusion:** The study examined policy decision-making process at multiple levels, analysing efforts to accommodate changing scientific evidence at a global scale and the requirements on country level policymakers to change national drug treatment policy.

The change and transition to ACTs have shown that innovation and creation of flexible instruments by the Global Fund required a balance; i.e. a balance between the desire to continually innovate before policies take into effect and repercussions of a system-wide effect in implementing Global Fund procedures at country-level. This is vital not only for changing malaria treatment policies but for all technological changes in light of new scientific evidence for the three diseases. Through the application of a theoretical approach from organisation studies, this research takes into question conventional thinking in public health and contributes to practice by generating insights and suggestions for how the Global Fund could move forward with the Learning Organisation Principles – improving organisational process and outcomes through a more effective learning process.

## EXECUTIVE SUMMARY

### Background

The Global Fund is an independent financing organisation formed in 2002 to fight against AIDS, Tuberculosis and Malaria by providing grant funds to countries. Country applications submitted to the Global Fund are reviewed by an independent panel and approved by the Global Fund Board and funds are disbursed based on performance achieved. For malaria, the Global Fund has provided funding support for the procurement of antimalarial drugs for treatment to endemic countries amongst support for other services. In 2004, malaria endemic countries had been successful in obtaining 63 grants totaling USD 483 million in support of malaria interventions over a two-year period. Of these, 44 grants include components for the procurement of antimalarial drugs which accounted for USD 60 million over two years and USD 118 million over five years.

In 2004, 14 countries adopted ACTs from a total of the 37 countries in Africa. However, the most rapid change took place between 1 January and 30 August 2004 due to increased funding from the Global Fund and international pressure leading to the shift to ACTs based on drug resistance data. The pivotal point stemming from international pressure came from a Lancet article published in January 2004, implicating the Global Fund for contributing to financing ineffective antimalarial drugs such as chloroquine (CQ) and sulfadoxine-pyrimethamine (SP), rather than the more effective ACTs. Similarly, WHO was cited for endorsing Global Fund proposals concluding that both "WHO and the Global Fund's current practices were not adequate to safeguard the best interest of malaria patients".[1] The article called for a rapid change to a more effective antimalarial drug (in particular to ACTs) and to accelerate efforts at country level.

In response, the Global Fund initiated a series of meetings in February 2004 with a number of stakeholders including the authors of the Lancet article and agreed to review the existing malaria grants. As a follow-up to the stakeholder meetings, the Global Fund spearheaded major reprogramming efforts focusing on the rapid creation of special instruments in order to address ACT transition for countries identified during the malaria review process.

[1] Attaran et. al, WHO, The Global Fund and Medical Malpractice in Malaria, The Lancet. Vol 363. January 17, 2004. p. 239

## Rationale for the Study

At the time the study was undertaken, there were limited data and literature on the performance-based funding approach especially in the public health field. The findings generated from this analysis can inform key areas of the public health literature (e.g. performance-based and results-based funding) and its associated professional practice (e.g. learning organisations) as well as provide insights into academic discourse interested in learning, knowledge and innovation.

The rationale for the study is to examine performance-based funding tools and frameworks used by the Global Fund and the effect on countries when special performance-based funding instruments (e.g. pooled financing, accelerated funding) were utilised. Specifically, the rapid reprogramming of malaria grants for the switch to ACTs and implementation efforts and its effects on performance-based funding was examined highlighting challenges faced by the countries requested to reprogramme.

## Aim and Objectives

The aim of the study was to develop a better understanding of the performance-based funding approach of the Global Fund and to examine its response to rapid change in treatment policies. Outcome of the study reflects the 'thinking' through the lens of Learning Organisations.

The main objectives of the research are to: gain a better understanding and insight into challenges and constraints of the Global Fund by examining the organisational structure and mechanisms related to performance-based funding approach; review and analyse key achievements of performance-based funding to date; review and analyse reprogramming of ACT as an example of performance-based funding; make appropriate recommendations to improve effectiveness of significant reprogramming[2] within the performance-based funding approach of the Global Fund; and reflect on the findings using the principles of the learning organisations.

[2] Significant reprogramming is defined as a change this is sufficiently substantive that questions the original intent of the approved proposal by the Technical Review Panel.

## Research Methodology

The thesis presents an organisational and policy analysis of the Global Fund from a historical perspective focusing on a period from its inception in 2002 to 2007. It documents processes of change, developments, and debates in a rapidly growing institution. Specifically, the study provides an in-depth examination of the trends of the Global Fund's performance-based funding approach over this five-year period. The literature review includes an examination of practices and approaches to date - from concept (its origins and rationale), to its implementation on a global scale, including assessment of its impact on end-user behaviour. The thesis draws on extensive literature reviews and contributes to the identification of complex multi-level issues affecting a global health initiative involving multiple partners.

Case study research methodology was applied for this research in order that the research can be based on the dynamic relationships between evolving scientific evidence of GHIs and the application of performance-based funding instruments. The research design for the malaria reprogramming is a mixed-method involving both quantitative and qualitative methods. The mixed methods approach to research enables a single research study to inform the complex nature of events from the participants' point of view as well as assessing the relationship between measurable variables. Triangulation was conducted by drawing from quantitative and qualitative data for the study. Narrative interviews and participant-observation methodologies were applied to document the organisational study as it unfolded and as a strategy to capture the "emergent" nature of the research adapting to new concepts and findings.

## Research Design: Quantitative Methods

Quantitative data on variables (e.g. grant profiles, country profiles) were pre-defined as categorical variables prior to the study. All approved malaria grants for Rounds 1-3 were reviewed for drug efficacy and financing information were compiled for approved anti-malarial drugs, in order to identify those malaria grants requiring a change in treatment policy. A total of 44 grants were reviewed with an antimalarial component and data collection was conducted for grant performance.

**Research Design: Qualitative Methods**

The qualitative research design was used based on phone interviews involving 27 Fund Portfolio Managers (FPMs)[3]. Semi-structured phone interviews were conducted between 2005-2006, one year after the reprogramming initiative. The FPMs were selected based on countries undergoing malaria reprogramming, which include a total of 26 countries with 2 FPMs assigned for Sudan (North and South Sudan) under review for Round 5 funding to seek clarification and other details on the on the grant making environment as part of the interview process.

A number of theoretical frameworks were used for analysis, based on the Learning Organisation model of Peter Senge as well as the frameworks of other learning organisation theorists (e.g. Hiddling and Catterall, Gavin, Jensen, Rowden) in order to analyse contributing factors for the evaluation of alternative approaches. Peter Senge describes the Learning Organisation in terms of Systems Thinking; Shared Vision; Personal Mastery; Mental Process Models; and Team Learning – characteristics, which can be seen in the internal workings of the Global Fund.

Several types of qualitative methods were applied: 1) Participant Observation seen as an important route to the development of theoretical and methodological foundation for research by Lüder (2004), in particular through extended participation method of Hammersley and Atkinson (1983) describing the participant observer and their relations in and to their field, the concept of positionality by Walt et al. (2009) and Merriam et al. (2001) on how a researcher is viewed or 'situated' in health policy research domain; 2) Narration referred by Yin (2009) as 'constructive validity'; narrative accounts described by Martin & Bauer (2007) as rich in indexical statements; and chronological dimension (i.e. narratives as a sequence of episodes); and non-chronological dimension (i.e. construction of a whole from successive events) by Ricoeur (1980) as well as the narrations of the FPMs for the malaria grants under review and, 3) reflective/reflexive empirical research methodology of Bourdieu and Wacquant (1992), where the researcher is seen as being inserted into a social field.

The positionality distinction is made between 'insiders' and 'outsiders' where the former may be both a participant and a researcher (i.e. participant observer). As a participant

[3] A total of 26 countries including N. and S. Sudan. There are 2 FPMs for Sudan.

observer, I was able to witness and document the events related to the Global Fund's malaria reprogramming process. I was also in a unique position to engage in extended participatory approach (i.e. a researcher's involvement in a range of activities over an extended period of time) to observe events and informal interviews, making notes of meetings, opinions expressed and conversations made in order to record and analyse how countries reached a decision to transition to ACT and the challenges encountered over the five-year period. This provided me with the opportunity to be an impartial observer but also to be personally involved at the same time. The positionality of the researcher as an insider provided me with the ability to "project a more truthful, authentic understanding of the culture under study" (Merriam et al. 2001), and thereby increase the validity of the study.

Narration as described by Martin and Bauer provides context based on a series of evidence that supports construct validity and ascertains whether operational variables are sufficiently represented by theoretical constructs. Reflexive empirical research of Bourdieu and Wacquant includes reflection and systematic interpretation. For the research on malaria reprogramming, I was able to follow the events chronologically over a five-year period, observing and recording a sequence of events from the time of publication of the Lancet article (i.e. the beginning or the origination of the story) to the outcome of countries which went through malaria reprogramming (i.e. the end point or the learning outcome as seen through the Learning Organisation lens) as an attempt to link time and the main events (chronological dimensions of reflexivity). I was also able to put together non-chronological construction of a 'whole' from successive events; from the time international pressure emerged in 2004 calling for a rapid change to ACTs, to the drug policy change process of countries, the global supply and demand side issues, partner coordination and technical support process, country ownership and related operational issues, review of performance of grants and the resulting policy implications related to a shift in scientific evidence and performance-based funding.

The reflexive nature of the research placing me at the centre of research allowed for free interpretations and reflections. Systematic reflection at various levels through the lens of learning organisations, i.e. examining the global, secretariat, and country levels, linking this information with embedded multiple unit analysis provided an in-depth picture of the research from examining consistent patterns of data for interpretation. By using these methods, I was able to capture multiple windows of events and the interconnections

based on systematic reflection (e.g. embedded multiple units of analysis) in order to reduce bias and increase internal and external validity. In addition, external and internal sources of data were utilised for related articles including online library catalogues, journals, periodicals, research publications as well as other meeting proceedings (e.g. Secretariat and country-level work experience, attendance and observation at Board meetings, regional and other partnership meetings, and other presentation materials).

**Findings**

The study provided insights into unintended effects of GHIs and various intervention complexities in malaria programmes within the health sector. Scaling up and intervention complexities for ACT reprogramming was attributed to a number of factors including: weak or lack of communication/coordination; short grant life span; reluctance of countries to change national drug policy; ACT implementation already in progress; limitation of grant size; problems with performance-based funding framework; implementation challenges including procurement delays; and, misclassification or site-specific implementation.

Based on the performance of the grants over a five-year period, only 4 countries made a decision to switch to ACTs (i.e. Nigeria, Angola, Gambia and Somalia) from a total of 22 countries which were requested to reprogramme in 2004. Follow-up from the Global Fund Portfolio Managers on the countries requested to transition to ACTs showed that many countries in fact, did not transition to ACTs at the pace expected by the Global Fund.

The majority of Global Fund grants earmarked for reprogramming suffered from reaching planned targets. A review of available Global Fund Grant Performance Reports and Grant Score Cards of the 26 countries,[4] including the 22 countries requested to reprogramme, 17 of the 26 countries (65%) under review showed poor performance indicators. All 17 countries with poor performance also showed that they were unable to reach the most important level 3 treatment indicator (also known as people reached indicator). The performance reviews of countries with malaria grants which were earmarked for reprogramming clearly showed that countries faced

[4] Chad and Malawi were excluded from the review. Chad did not reprogramme and Malawi had no progress indicators.

procurement delays due to global shortages of ACT commodities. At least 14 of the 17 countries (82%) experiencing underperformance had difficulties with ACT procurement.

The lack of programmatic progress and achievement for malaria during 2004-2006 were evident by the fact that an improvement in results were gradually witnessed only in 2006 with an increase from 60% to 73-77% after Phase 2 evaluation[5][6] where past performance is taken into consideration by the Technical Review Panel when reviewing new proposals. The challenges faced by many countries, mainly due to external factors (e.g. ACT reprogramming efforts, global supply shortage of commodities, limited supplier selection), directly affected the success of future rounds of malaria grants.

Subsequently, the success rate for malaria grants was cited as being the lowest for Global Fund Round 5 and Round 6.[7] Some of the main reasons cited was a global supply shortage of commodities including ACTs due to limited supplier selection, quantification and procurement delays. As a result, many countries were not able to show achievement for a number of important treatment coverage indicators. Only 4 countries (14%) out of the 28 countries that applied to Round 5 were successful in their proposal application to the Global Fund. One country (Guinea) succeeded through an internal appeal process where the TRP reversed their decision. Seventeen of the proposals were marked Category 3 (not recommended for funding but strongly encouraged to apply) and one was marked Category 4 (not recommended for funding). Similarly, for Round 6, of the 24 countries which applied, 6 countries (25%) were successful in securing Round 6 funding. Sixteen countries received Category 3 and 2 countries received Category 4 ratings. For both Rounds 5 and 6, there was an 80% failure rate for all the malaria proposals submitted by the countries earmarked for reprogramming.

The qualitative data obtained from the interview process with FPMs provided contextual information to identify the process, challenges, constraints and outcomes of reprogramming. It also provided a valuable supplement to the analysis process (e.g. grant score cards, and grant performance reports) undertaken for Phase 2 renewal decisions for funding.

[5] The Global Fund grants are approved for a five-year period; however, the funding is committed for an initial two years period (also known as Phase One). The Global Fund's Phase 2 review process is enacted to evaluate achievement of performance indicators and targets for decision on continued funding for the remaining years of the grant.
[6] The Global Fund. Partners in Impact, 2007. p. 47.
[7] The Global Fund round-based grants are based on calls for proposals by the Global Fund, where proposals are received and reviewed by the Technical Review Panel and are approved by the Global Fund Board.

From a Learning Organisation perspective, the research looks at the evolving framework of operational policies of the Global Fund, which describes efforts to improve the output and quality of an organisation and its performance and practices. The Global Fund was created as a "new learning organisation" based on the experiences of other global partnership initiatives and described as a "flexible organisation" continuously learning based on its existing knowledge and using this knowledge to improve its processes. By employing the learning technique of “learning by continuous improvement” in the operational processes, the Global Fund was able to address improvements in its guidelines and operational processes within short periods. Performance-based funding framework and operational tools were also developed within this flexible environment.

The research utilised embedded multiple units of analysis, within a single case design or within an embedded design. Yin (1994) cites that a research study may include the main as well as smaller units on different levels striving to look for consistent patterns of evidence across units but within the same case design. The multiple units of analysis were conducted with a focus on three levels: a) at the Global level by examining Global partnerships and issues related to coordination of ACT production and supply at the global level; b) at the Global Fund Secretariat level by examining the organisational structure, decision-making process as well as performance of PRs; and c) at the country level by examining coordination and implementation challenges.

**Discussion**

The paper outlined some of the elements of scaling up as defined by Hanson et al. (2003) in terms of issues related to: 1) health service delivery and in particular, procurement, quantification and supply chain management issues; 2) health sector policy and strategic management formulation (i.e. policy options for informed decision making process); and 3) cross-cutting public policies and understanding intervention complexity. Implementation challenges at country level, the delays related to effective coordination at the global partnership level, and in providing required technical guidance and coordination resulted in implementation delays at country-level. The lack of proper procurement planning further hindered implementation and directly affected performance of Global Fund malaria grants.

The switch to ACTs highlighted challenges faced by all countries which had undergone the transition process and evidenced by the lack of anticipation and proper planning for the transition process. The key challenges reflect the sheer complexity of a rapid change in policy as well as building consensus around the evidence amongst the global and in-country partners.

Performance-based funding is an important instrument and can act as a catalyst; however, in the case of malaria reprogramming and the rapid switch to ACTs, creation of special instruments alone regardless of its innovation and flexibility did not facilitate the change or desired outcomes at country level. Low-Beer et al. (2007) also caution that PBF may penalise poorer countries, and may not be flexible enough to contribute to health systems generally.

**Key Findings for Research, Policy and Practice from the Study**

Intervention complexities, system-wide effects, and fragmentation as a result of GHIs especially within the context of vertical programme implementation at country level should be reflected with the recognition that application of a one size fits all performance-based measurement approach for a rapid policy change can have negative effects for countries which are trying to achieve results and for securing future funding based on past performance indicators.

The findings show that there is a need for closer coordination for consensus building, and to meet immediate and future technical assistance requirements. Sufficient lead time for TRP Briefing, and for orientation of new TRP members are essential for future grant proposal review as well as FPMs. The Global Fund's funding decisions should be grounded in advance planning and procurement coordination together with stakeholders. Special considerations should be provided for PBF within significant reprogramming for Phase 2 grant renewals along with new rounds of applications including weighting for contextual information should be adjusted to reflect realistic achievement of performance-based indicators.

Learning Organisation model of Peter Senge[8] and other theoretical frameworks of learning organisation theorists (e.g. Hiddling and Catterall, Gavin, Jensen, Rowden etc.), show that organisations have different learning techniques. Among the different types of organisation learning (e.g. competitive acquisition, experimentation, continuous improvement, boundary sharing),[9] the Global Fund exercised the experimentation and continuous improvement models by striving to implement various experimental models (innovation) such as the performance-based funding,[10] and lean grant management approach, flexibility with procurement guidelines, flexibility in appointing multiple PRs, and harmonising funding procedures to simplify donor fund flows.

**Conclusion**

The study examined policy decision-making process at multiple levels, analysing efforts to accommodate changing scientific evidence at a global scale and the requirements on country level policymakers to change national drug treatment policy.

The changes and transition to ACTs have shown that innovation and creation of flexible instruments by the Global Fund even within the context of normal operational framework such as reprogramming, required a balance; i.e. a balance between the desire to continually innovate before policies take into effect and repercussions of a system-wide effect in implementing Global Fund procedures at country-level.

The Global Fund initiated the ACT transition process, which, on one hand, acted as a catalyst for global level coordination efforts along with Roll Back Malaria partners. On the other hand, external forces and other constraining factors such as limited pre-qualified suppliers, production needs, lack of producer confidence in forecasting and quantification efforts to guarantee orders, and reluctance of countries to switch to ACTs led to difficulties in planning, which ultimately resulted in a global shortage of ACTs.

A learning organisation lens (systems thinking, personal mastery, mental models, building a shared vision and team learning) which was applied to analyse the Global Fund at multiple levels: the Global Fund Board level (e.g. Board policy changes); Secretariat level (e.g. organisational and structural changes); and, at country level (e.g.

[8] Peter Senge and the theory and practices of the learning organisation. http://www.infed.org/thinkers/senge.htm
[9] Cook and Hunsaker, 2001, p. 552.
[10] Performance-based funding has been employed by various technical and donor agencies, e.g. USAID, CIDA and other NGOs for certain projects but has not been implemented on a large scale.

changes to proposal guideline process, grant signing process, PR arrangements, the fiduciary and programmatic management process of the LFAs), has shown that PBF is an important instrument and can act as a catalyst for the Global Fund. However, this research has also shown that the creation of special instruments alone was not sufficient for the successful implementation of the switch to ACTs. As a learning organisation, the Global Fund will need to continue to leverage on creative innovative mechanism for malaria (as in the case of ACT reprogramming) and other new treatments.

Taking lessons from the change in malaria treatment policies, global and country level implementation challenges must be taken into account which addresses adequate planning for both technical and financial requirements. The Global Fund working together with partners and the broader community will need to provide countries with policy options in order to make appropriate policy choices and ownership at country level. This is vital not only for changing malaria treatment policies but for all technological changes in light of new scientific evidence for the three diseases.

Through the application of a theoretical approach from organisation studies, this research takes into question conventional thinking in public health and contributes to practice by generating insights and suggestions for how the Global Fund could move forward with the Learning Organisation Principles – improving organisational process and outcomes through a more effective learning process.

"*Performance-based funding is nothing new but few have been as rigorous in the application of the principles"*
*(Multilateral representative)*

"*The Global Fund is de facto influencing policy in a country by investing so many resources. There is no way that the Global Fun can function only as a 'neutral' financing instrument"*
*(Multilateral representative)*

*"The Global Fund's major achievement has been to prove that what many people considered as impossible was possible – namely to bring treatment to a large number of people"*
*(Government representative – recipient country)*

*"The Global Fund is probably the best large-scale international development model ever. It faces challenges at every turn…*
*(Respondent, on-line Stakeholder Survey)*

*"There is a need to look at unintended effects at country level – what the Global Fund has done to governments, civil society and other donors"*
*(Multilateral representative)*

*"There is no doubt that the Global Fund provides countries with golden opportunities to scale up interventions that target killer diseases. However, the effect of such rapid performance-based funding might further disintegrate health systems that were already weak"*
*(Respondent, on-line Stakeholder Survey)*

*"There is a critical trade-off in the Global Fund – between reaching short-term benefits versus long-term, sustainable benefits"*
*(Multilateral representative)*

(Selected quotes from 360°stakeholder assessment)

## SECTION I: INTRODUCTION

This doctorate thesis has been submitted as part of the requirement for the Doctorate in Public Health degree at the London School of Hygiene and Tropical Medicine. The paper provides an overview of performance-based funding utilised in other health sectors and makes linkages to performance-based funding tools and frameworks used in more recent global initiatives, including but not limited to, the Global Fund. It provides background on the performance-based funding approach including reprogramming as a performance-based funding instrument.

The content of the paper is derived from an organisational analysis of the Global Fund, which was set up in 2002. The objectives were: 1) to gain a better understanding and insight into challenges and constraints of the Global Fund by examining the organisational structure and mechanisms related to performance-based funding approach; 2) to review and analyse key achievements of performance-based funding to date; and 3) make appropriate recommendations to improve effectiveness of significant reprogramming within the performance-based funding approach for the Global Fund using reprogramming of ACT as an example.

The paper is a result of research work conducted from October 2002 to October 2007 at the Global Fund based in Geneva, Switzerland. It is the largest global fund of its kind, with approximately USD 9.7 billion pledged through 2008 by 45 donor countries, foundations and the private sector. Since its inception in 2002, the Global Fund has made considerable progress in setting up its Secretariat, putting systems and procedures in place. As of 2006, the Global Fund Board had approved USD 5.1 billion for 385 grants to 130 countries.[11] As of June 2006, 544,000 patients have been put on ARV treatment, 1.43 million persons have been reached with TB DOTS, 11.3 million ITNs have been distributed and 7.3 million people have been provided with antimalarial treatments (including 2.5 million with artemisinin-based combination therapy)[12].

The Global Fund was created as a "new learning organisation" based on the experiences of other global partnership initiatives striving to achieve a balance between being a financial instrument taking into account implementation concerns without being an implementing agency. The Global Fund has claimed to be a "flexible organisation" continuously learning based on its existing knowledge and using this knowledge to

[11] The Global Fund. Press Release. April 28, 2006.
[12] Investing in Impact, the Global Fund, 2006.

improve its processes. The strength of the Global Fund laid in dynamic teams functioning within a flexible and innovative environment to develop new ways of working to continually improve its processes. By employing the learning technique of "learning by continuous improvement" in its operational processes, the Global Fund was able to address improvements in its guidelines and operational processes within a short period. Performance-based funding framework and operational tools were also developed within this flexible environment.

The goal of the paper was partly to analyse the extent to which the outcomes reflect the Learning Organisation Framework. The aim of the study was to develop a better understanding of the performance-based funding approach of the Global Fund and to examine its response to rapid change in treatment policies. The outcome of the study reflects the 'thinking' through the lens of Learning Organisations. Contribution to practice would be to generate insights and suggestions on how the Global Fund could move forward the Learning Organisation Principles – improving organisational process and outcomes through a more effective learning process.

This paper examines the organisational framework of the Global Fund between 2002-2007 with a specific focus on performance-based funding approach, elements of reprogramming and implications of significant reprogramming within the Global Fund. The assessment examines the implications of significant reprogramming through a case study of the transition to ACT in 30 of the Global Fund malaria grants, based on a review of a total of 44 grants with an antimalarial component. The drug efficacy review focused on 30 grants transitioning or not using ACTs at that time.[13] The paper highlights the process and subsequent outcomes of reprogramming these grants.

Research findings show that although the country recipients were provided with the necessary tools required for the transition (e.g. funding and the provision of flexible reprogramming tools), the unanticipated challenges stemming from significant reprogramming became evident. Since the Global Fund was established in 2002, it has approved a total of 123 grants to 73 malaria endemic countries. By May 2006, the Global Fund had contributed 64% of all international funding for malaria. The impetus of an institution responsible for USD 1.6 billion over a two-year period in 73 countries and 2.6 billion over the lifetime of the grant with approximately 50% of these funds to be used

[13] The review excluded 11 grants already requesting ACTs, and 3 grants which do not need a transition to ACT.

towards procurement of malaria commodities gave way to more than an institutional challenge. It also brought forth the realities of external factors associated with global partnership and interagency collaboration, country-readiness, global demand and supply side issues (e.g. production and supply of ACTs and the need for forecasting).

This paper is divided into eight sections. Section I outlines the introduction. Section II describes performance-based funding utilised in other health sectors and makes linkages to performance-based funding tools and frameworks used in the more recent global initiatives, including but not limited to, the Global Fund. It provides background on performance-based funding approach, which includes reprogramming as an instrument of performance-based funding.

Section III describes the approaches (study of research methods) applied, including the aim of the study, objectives, data collection methodologies utilised and country selection criteria including the malaria review process. Country selection criteria were based on the approved malaria grants for Rounds 1-3 with an anti-malaria component. Section IV describes the background, genesis, the organisational and operational framework, and proposal approval process of the Global Fund. Section V outlines the performance-based funding approach including instruments used to measure performance and the four levels of performance-based funding framework. This Section includes Global Fund's "phased" grant renewal processes (Phase 2 funding), and performance to date (i.e. taking a look at results achieved of grants which have undergone Phase 2 grant renewals), data quality review process and other new instruments such as Rolling Continuation Channel (RCC), created for countries with the well performing grants.

Section VI provides background on ACT and outlines the chronological events which led to the shift to ACT reprogramming of Global Fund grants, specific tools created within the Global Fund Performance-based Funding framework to facilitate ACT reprogramming efforts, demand side issues (e.g. country perception of the transition, concerns regarding financial sustainability, the Global Fund's initiative in driving the process, and partnership collaboration in this effort). The supply side issues and the effects on ACT producer behaviour, implications of suppliers and the challenges of barriers to entry (e.g. pre-qualification process). Section VII outlines the case discussion in reviewing the elements of reprogramming at the global level, Global Fund Secretariat level and country level highlighting global partnership issues, key achievements,

challenges, and constraints. The Section takes into account global partnership issues in addressing ACT (e.g. the formation of new global initiatives to address the need for better coordination and forecasting, pooled financing and pooled procurement), system-wide effects of reprogramming, long-term sustainability issues, followed by recommendations. Section VIII covers the analysis and recommendations and Section IX for conclusions.

## SECTION II: PERFORMANCE-BASED FUNDING

Heinrich (2007) cited that although performance management as a management tool in organisations has a long history dating back to the 19th century, it was only in the past two decades that government performance management has adopted the explicit aim to regularly and more rigorously measure outcomes and report results to the public. He noted that the rise of development of performance management systems and practices has been nothing short of meteoric; both nationally and locally, performance management is now a goal or function of most governmental and nongovernmental organisations, and in many countries, legislation and cabinet-level entities have been created to support this approach. He described evidence-based policy and performance management appear to share a fundamental goal: to improve government effectiveness by developing and using a more rigorous approach of information and scientific evidence to guide decisions about programme design, funding, implementation, and management.[14]

He further stated that in ideal circumstances, governments would use a full range of information in decision/policy making a logical flow – from data on inputs and processes (e.g. staffing, resources, core technologies, procedures) to outputs (e.g. provision of services), and from performance outcomes (intermediate results) to impact, which is value added estimated through comparison with consequences of policy or interventions if it had not been implemented. It links performance monitoring of ongoing processes and results to the impact evaluation and cost-effectiveness. In practice, there are some important differences between the approaches of these two movements to achieving this common objective such as their methods and standards for assembling and analysing data, and the timing and use of this information to influence policy and accountability for performance.[15]

Kasdin (2010) points out that by not specifying incentives, programme elements are rewarded based on those that get the most reaction from the public, rather than based on programmatic needs. In general, if the basis for rewards for programme management

[14] Heinrich, 2007, p. 256
[15] Ibid., p. 256

comes from political support, not performance measure improvements, then performance measurement is considered to be ineffective.[16]

Similarly, performance-based payment systems have long been utilised in the private sector and many other sectors including education and IT sectors. Performance-based payment systems aim to improve provider performance in light of costly monitoring considerations with well-defined benchmarks and performance indicators for achieving targets. Despite the long-standing practice, introduction of this performance-based funding approach was still in its nascent phase in the global health domain and there was little evidence to support its application in the not-for-profit sector.

## A. Application of Performance-based Funding in various sectors

### a. Performance-based funding within bilateral agencies (USAID)

USAID's work began with Defense contracting known as Federal Acquisition Rules and Regulations (FAR). FAR became effective on April 1, 1984 under the joint authorities of the Administrator of General Services, the Secretary of Defense and the Administrator for National Aeronautics and Space Administration, Office of Federal Procurement Policy, and Office of Management and Budget.[17] FAR is the main regulatory document used by all Federal Executive agencies in their procurement activities. However, FAR's policies and procedures were seen as inadequate by many implementing agencies which include but not limited to the following reasons: 1) inconsistency in review and approval of performance-based payments 2) inappropriate valuations; and 3) and lack of knowledge on how to structure performance-based payments.[18]

A number of other mechanisms were also developed including fixed obligation grants and fixed amounts reimbursable agreements (FARA). Fixed obligation grants were based on milestone payments on accomplishment of benchmarks[19] rather than contract-based payments. The assumption for the milestone approach was based on the fact that if the commodities are the same (with the proviso that there is little likelihood of

[16] Kasdin, 2010, p. 58
[17] FARSmarterBids.com, 2010. www.farsmarterbids.com/regs/fars/info.php?
[18] Federal Register, Vol. 70, No. 105, June 2, 2005/Notices
https://www.federalregister.gov/documents/2005/06/02/05-10910/contract-financing-performance-based-payments
[19] Aqaba Community and Economic Development (ACED) Program. USAID. http://aced-jordan.com/faq/item/67

fluctuation), then procurement can be carried out on credit, on a reimbursable basis with pre-arranged prices.

Fixed Amounts Reimbursable Agreement/Method (FARA): FARA is the most commonly used method for many of the USAID-financed projects, particularly for low cost, short-term projects or for sub-components of a project. The distinction between FARAs and other disbursement schemes is that the reimbursement is made for outputs rather than inputs, i.e., reimbursement is made upon completion of a project or a sub-component of a project. FARA is based on conformance of outputs to previously agreed upon specifications or standards. The amount of reimbursement is fixed in advance based on reasonable cost estimates, which has been reviewed and has received prior approval.

Performance contracts versus results-oriented grants have a termination clause for mutual agreement or material breach of agreement. In the US, President Clinton signed the Government Performance and Results Act (GPRA) of 1993 into law with a promise to measure progress and hold federal agencies accountable for their results. Agencies are required under GPRA to establish performance goals, measures, and plans to provide evidence of their performance relative to targets, and to report their results annually to the public.[20] GPRA required all agencies prepare and annually submit performance measures as part of their budget submissions to Congress.[21] Since the start of GPRA in 1993, there has been growing new research in public administration and evaluation, in economies dealing with optimal contract design and principal-agent theory, and in political science in looking at institutions and organisational design.[22]

The principle of Performance-based Funding essentially eliminates process specific approach and focuses instead on desired outputs. Additional performance measures are put in place such as a Quality Assurance Surveillance Plan as well as incentives and disincentives structures reflected in Performance-based services contracts.

In November 2007, the Bush administration released an Executive Order “Improving Government Programme Performance” that continues to develop the GPRA.[23] On April 2010, the Obama Administration issued an Executive Order, “Establishing the

[20] Heinrich, 2007, p. 258
[21] Kasdin, S., 2010 p. 52
[22] Ibid., p. 53
[23] The White House, George W. Bush, Office of the Press Secretary, November 13, 2007 https://georgewbush-whitehouse.archives.gov/news/releases/2007/11/20071113-9.html

President's Management Advisory Board," as well as creating an interagency evaluation working group in 2009, led by the Office of Management and Budget (OMB), tasked with programme performance evaluation.[24] The OMB reviewed the effects of GPRA and found that after eight years of experience; progress toward the use of performance information for programme management has been discouraging.

According to GAO survey of federal managers, agencies, may, in fact, be losing ground in their efforts to building organisational cultures that support a focus on results.[25] Problems with GPRA include: multiple goals and complex objectives; lack of benchmarking and multiple principals (e.g. programme goals as political compromise, commitment problems); political based determination of agency funding; and lack of any direct incentives to the performance measures.[26]

### b. Conditionality, Aid Effectiveness, and Performance-based Funding of Global Health Initiatives

Morrissey (2002) cites that aid can contribute to growth in two basic ways: aid flow by relaxing financing constraints (e.g. government budget); and, by using conditions attached to aid. The effectiveness of conditionality, i.e. the extent to which the reforms advocated by donors are in fact implemented, is mediated by the recipient government's willingness to accept the conditions and its ability to implement them.[27]

Shepherd (2002)[28] describes this performance approach as an "output-based approach to aid" whereby donors and/or government contract service delivery to third party entities that tie payment to particular outputs. This approach (based on the principle-agent theory[29] in economics) is seen as a new approach, which delineates from the traditional "input-based approach to aid" – i.e. tying recipient governments to an agreed set of services with upfront payment for the necessary inputs for service delivery. The weak provisions to enforce this agreement within the input-based approach, have led the aid

[24] Ibid., p. 52
[25] Office of Management and Budget, 2001 p. 27
[26] Kasdin, S., 2010 p. 55
[27] Morrissey, O., 2004, p. 154
[28] Shepherd, G. 2002. Delivering Project Aid in Old and New Ways: Institutions Matter. http://rru.worldbank.org/documents/OBADelivery_Sheperd.doc. downloaded November 26, 2003.
[29] Both principle and agent obtain what they want at acceptable levels of transaction costs.

community to look for other alternatives in search of a “new way of doing business” in order to improve efficiency and increase accountability for performance.

The Monterrey Consensus Agreement adopted by heads of state at the International Conference on Financing for Development in Monterrey, Mexico in March 2001 signalled a new partnership between donor and recipient countries aimed at achieving the Millennium Development Goals (MDGs). It recognised that the main responsibility for accelerating development lies with implementing countries and that they cannot achieve these goals without the cooperation and assistance of the international community.[30]

Conditional lending, specifically through structural adjustment loans, became the standard of donor aid policy in the 1980s. Morrissey (2002) and Radlet (2004) noted that International Financing Institutions such as the International Monetary Fund (IMF), the World Bank, Asian and African Development Banks use similar systems. For example, the World Bank developed a Performance Based Allocation system as the basis for distributing its International Development Association (IDA) funding, which in part relies on the Bank’s rating of each country’s policies, institutions, and governance.[31]

However, Morrissey (2002) pointed out that the strategy was found to be somewhat less than perfect in the early 1990s when conditional lending (e.g. IMF conditionality or World Bank structural adjustment lending) was proven to be an ineffective mechanism to induce reform from unwilling governments and was seen as an inappropriate mechanism if governments were willing to reform (e.g. measuring compliance through the use of tight implementation mechanism or unclear outcome indicators with policy inputs).[32]

Although bilateral assistance agencies such as United States Agency for International Development (USAID) and Canadian International Development Agency (CIDA) have played a leading role in the use of this approach, implementation has been carried out in selected small-scale programmes and countries. Different methodologies have also been applied within these programmes (e.g. an incentive structure based upon bonuses on achievement targets). A systematic application of various methodologies was first initiated by the Global Alliance for Vaccines and Immunisations (GAVI), focusing on one specific target indicator - immunisation coverage, and later Global Alliance in Nutrition

[30] Radlet, 2004, p. 2
[31] Ibid., p. 9
[32] Ibid., p. 155-163

(GAIN) which focused on maximising micro-nutrition, coverage for the poor to increase productivity and improve cognitive development of school children. The Global Fund is one of the organisations that adopted a comprehensive performance-based funding approach on a global scale to monitor numerous planned performance targets for the three communicable diseases within the health sector.

In a March 2006 report of the Chair of the Development Assistance Committee on Health Aid Architecture, the approaches utilised by the Global Fund and GAVI were highlighted as examples[33] to be considered within the structure and framework of the Paris Declaration on Aid Effectiveness, which is based on the principles of ownership, alignment, harmonisation, managing for results and mutual accountability.[34] The report drew attention to the performance-based cultures of the two organisations and the associated challenges within the health sector. These new global organisations were mandated to provide early results, innovative approaches and show additionality.

The following section describes the organisational structure, functions, and performance-based funding framework of three Global Initiatives: GAVI, GAIN and the Global Fund. The performance-based funding approach for the Global Fund will be described in more detail in Section V.

### c. Performance-based funding framework of three Global Initiatives:

#### i) Global Alliance for Vaccines and Immunization (GAVI)

GAVI is a public-private initiative created in 2000 to improve access to immunisation for children. The GAVI alliance is comprised of UNICEF, WHO, the World Bank, the Bill and Melinda Gates Foundation, NGOs, vaccine manufacturers, public health and research institutions.

GAVI serves as an alliance of agencies concerned with immunisation issues in developing countries, for coordination, priority setting and policy development. In addition, GAVI also sets policy and utilisation of additional funds for vaccination raised by the Vaccine Fund. The Vaccine Fund was set up by GAVI partners to maintain significant new financial support.

[33] IMF and the World Bank (2003). Development Committee Progress Report. December 2003-0004
[34] Organisation for Economic Co-operation and Development. Downloaded on July 2005. http://www.oecd.org/document/18/0,3343,en_2649_3236398_35401554_1_1_1_1,00.html

GAVI's structure includes a Board, a Working Group that serves as an advisory body to the Board on technical issues and provides linkages with partners and other key agencies. GAVI Secretariat provides administrative support to the Board and the Working Group and an Independent Review Committee (IRC) and Task Forces provide proposal reviews and recommendations to the Board. The Vaccine Fund has a separate Board and management team.

The objectives of GAVI are to protect children of all nations including all socioeconomic levels against vaccine-preventable diseases. Its six strategic objectives are to: 1) improve access to sustainable immunisation services; 2) expand the use of all existing safe and cost-effective vaccines; 3) promote delivery of other appropriate interventions at immunisation contacts; 4) support the national and international accelerated disease control targets for vaccine-preventable diseases; 5) accelerate the development and introduction of new vaccines and technologies; accelerate research and development (R&D) efforts for vaccines needed primarily in developing countries; and, 6) make immunisation coverage a central platform in international development efforts.[35]

GAVI has set its milestones to achieve 90% routine immunisation coverage at the national level with at least 80% coverage in every district in all the selected countries by 2010. In order to achieve the results, GAVI put in place the following key features and requirements as part of their monitoring and evaluation process.[36]

**Call for Proposals:** There is a proposal review process where new proposals are received at the GAVI Secretariat. An Independent Review Panel comprised of 9 experts in health and immunisation is responsible for reviewing and making recommendations to the Board. Eight members are from low-middle income countries.

**Financial Sustainability Plans:** All countries were required to develop financial sustainability plans during the second year of the Vaccine Fund to be reviewed by a team of the Independent Review Committee (IRC). GAVI facilitates training workshops in order to assist countries in the development of their financial sustainability plans.

[35] The Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund. Fact Sheet. February 2005
[36] The Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund. Fact Sheet. April 2005

**Annual Progress Reports:** The monitoring team of the Independent Review Committee (IRC) reviews the reports and provides recommendations for approval to the GAVI Board. A satisfactory annual progress report is required for continued support by GAVI.

**Data Quality Audit (DQA):** GAVI implemented DQAs in its early stages which have been developed by WHO, to assist with the evaluation of the quality of a country's health information system and verify the accuracy of reported data. DQAs are conducted in countries receiving Immunisation services support during the first or second year of funding.

The DQA was conceived as a means to verify reported performance as well as enhance Immunisation monitoring and reporting systems. It reviews both the numbers of children reported to have received a DTP3 injection and the accuracy of the Expanded Programme on Immunisation (EPI) reporting system. Effective programmes with accurate data recording and reporting systems receive the most credit in a DQA.

Accurate data recording and reporting practices are required for: 1) managers of immunisation services to track progress on performance; 2) GAVI Alliance partners to determine the impact on performance; and, 3) determining and awarding incentives. For the latter, GAVI provides incentives based on a system of shares. One share is earned by a country for each additional child reported to have been immunised compared to baseline or the previous year.

The DQA however, is considered to be relatively costly (approximately USD 45,000 per audit) as this process is conducted by external auditors. Due to the cost factor, DQA can only include a relatively small sample size. The information collected from a DQA enables auditors to offer advice to health workers, and national EPI programme managers. DQA also serves as a capacity building tool for improving immunisation information systems.

Both the sampling method and the sample sizes are validated independently by statistical experts from Ohio State University for the required number of districts in a country. The random selection method also provides a representative picture of the country’s monitoring and reporting systems. In addition, due to the small sample size (i.e. 4 districts and 24 health units) a country can undertake corrective measures in all the identified sites.

Although it is acknowledged that measurement of DQAs is not sufficiently precise, the measures including the verification factor (VF) have very large confidence intervals, greater than +/-20% (at the 95% confidence level) with the width increasing with intra and inter district variability**.** The threshold approach set at (80%) is used to determine access to rewards leaving a 20% verification gap. The approach allowed 50% of 16 countries audited in 2002 to be eligible for rewards. If a country's VF is below the threshold, there is an opportunity to conduct a coverage survey, in order to allow the country to be eligible for rewards for one year.[37]

The verification factor significantly correlates with the quality indices at health unit and district level, i.e. lower VFs would indicate weaker monitoring systems. Whilst acknowledging that one single measure is not intended to solve all the problems, attention was given to examining weaknesses at district units and at national levels. The DQA briefing papers are made available to the Interagency Coordinating Committee (ICC). The countries are then requested to review different indicators for the quality of its monitoring systems (e.g. variance between different coverage estimates, reporting completeness, etc.) in order to determine weaknesses and areas for improvement. Data quality assessments and supervisory checklists are two tools that are used for diagnosis.

The ICC reviews the recommendations and prepare an action plan to be included in the next GAVI annual report. Actions are discussed with the Regional Working Group and other implementing partners. A systematic follow-up based on the findings and recommendations of the DQA is crucial and is one of the key actions for the countries to strive for improvement of coverage.

### ii) Global Alliance in Nutrition (GAIN)

GAIN was set up in May 2002 at the UN Special Session on Children as a global and regional alliance of private and public sector partners, with a view to maximise fortified food (micro-nutrition) coverage for the poor to increase productivity and improve cognitive development through school feeding programmes. It also aims to significantly reduce birth defects in new borns. Food fortification, linked with other initiatives such as agribusiness, small business development and poverty reduction strategies, was seen as potential linkages for poverty reduction.

[37] The Global Alliance for Vaccine and Immunization. How to prepare for Data Quality Audit Briefing Paper. May 2002.

An initial start-up grant was provided by the Bill & Melinda Gates Foundation with additional funding from United States Agency for International Development (USAID) and Canadian International Development Agency (CIDA), channelled through the Micronutrient Initiative. GAIN became operational at the end of July 2003 with the World Bank serving as GAIN's interim trustee. GAIN's Strategic Plan was developed and presented to the Board in October 2003.

**Call for Proposals:** Request for Proposals is made through the GAIN website. An independent Proposal Review Panel then reviews proposals with recommendations presented to the Board. Appraisal process began in March 2003 for the first 5 projects, awards were made in March and in December 2003. GAIN opted for a dual-track implementation approach whereby GAIN took on responsibility for implementation of a number of projects and the World Bank for implementing 10 projects.

By early 2005, GAIN raised USD 60 million in core funding, awarded 23 grants worth USD 38 million, and established 15 national food fortification programmes, projected to reach 450 million people over a three-year period to cover 293 million who are at risk of vitamin and mineral deficiencies. GAIN stimulated commitment by the food industry to invest USD 353 million in fortification and raised awareness regarding food fortification in the developing world.

GAIN put in place a new management framework in mid-2005 to accelerate programme delivery and enhance partnership collaboration between development partners, the food industry and consumer groups. The objective of GAIN's business plan was to achieve rapid and efficient programme delivery focusing on five main areas:[38]

- **Grants management and technical assistance programmes** - new rounds for competitive grant applications, tailored projects for large countries, a small grants facility to address bottlenecks, and technical assistance to support project implementation.
- **Business and consumer programmes** - operational partnerships with industry, a world-wide support network for business leaders, and collaboration with the global consumer movement.

[38] Global Alliance in Nutrition. Framework Document. November 2005

- **Special programmes** – start-up investment to empower new project areas: such as special initiatives in Africa; infant and young child feeding; fortification of school meals; bringing new products to market; broad sectoral planning and campaigning; fortification of food aid; and affordable access to premix and fortificants.
- **Performance measurement and monitoring programmes** – design and implementation of a comprehensive framework to measure and report health impacts and coverage in target populations.
- **Communication programmes** – global advocacy, communication and social marketing support to projects, and corporate communication.

GAIN also put in place competitive grants stimulating the establishment of 15 national food fortification programmes. Small Grant Schemes were utilised to resolve implementation bottlenecks for large-scale food fortification process. GAIN allocated 7 grants to countries, 3 to regional partners and 3 to global partners.

GAIN mirrors the Global Fund in its country driven processes and performance-based funding framework. There is a call for proposals once a year and it is reviewed by the Technical Review Panel (TRP). In-country processes are supported by the National Fortification Alliance (the equivalent of the Global Fund's CCMs) and in-country advisors (the equivalent of the Global Fund's Local Fund Agents). Similarly, GAIN Board was also based on a "constituency model" of the Global Fund Board consisting of one NGO representative, one industry representative, one scientific community representative, one UN representative, one bilateral donor, one representative of the Gates Foundation and four developing country representatives.

GAIN engaged United Nations Development Programme (UNDP) as its host agency with the rationale that UNDP with its experience in partnership development as well as the serving as the lead agency in the United Nations Development Assistant Framework (UNDAF) would have major convening and facilitating capacity to bring together all relevant agencies (e.g. WHO, UNICEF, FAO, UNIDO, WFP) in order to work towards the MDGs[39] and to promote private-public partnership.

[39] Specifically, for Goals 1 and 8: Goal 1, eradicating extreme poverty and hunger, and Goal 8, on developing a global partnership for development.

### iii) The Global Fund

The Global Fund was set up in January 2002 and is an independent, public-private partnership with a focus on country ownership and country driven processes designed for responsive, efficient disbursement of funds to countries affected with HIV, Tuberculosis and Malaria. As of April 2006, the Global Fund has approved USD 5.1 billion to 385 grants implemented in 130 countries.[40]

The principles of the Global Fund are to: operate as a financial instrument, not an implementing entity; make available and leverage additional financial resources; support programmes that reflect national ownership; operate in a balanced manner in terms of different regions, diseases and interventions; pursue an integrated and balanced approach to prevention and treatment; evaluate proposals through independent review processes; establish a simplified, rapid and innovative grant-making process and operate transparently, with accountability.[41] The Global Fund financed projects are implemented through the CCM, PR and the LFA.

The CCM is a country level multi-sectoral body that coordinates proposals to the Global Fund. The CCM selects the PR and monitors the implementation of activities under approved programmes, including approving significant changes in implementation plans as necessary. The CCM also evaluates the performance of a programme, submits a request for continued funding prior to the end of the two years of the initially approved funding from the Global Fund (also known as Phase 2) and ensures coordination and harmonisation with other in-country programmes.

The PR is the entity legally responsible for grant proceeds and implementation in a recipient country. The PR is responsible for programmatic results and legally accountable to the Global Fund for all grant funds. The PR is selected by the CCM and confirmed by the Global Fund. There may be multiple public and/or private PRs in a single country and in a single disease component.

Once the PR is confirmed the Global Fund will negotiate a two-year agreement in which disbursement of funds is based on achievement of measurable results. The Global Fund

[40] The Global Fund. Press Release. April 28, 2006.
[41] The Global Fund Framework Document, 2002.

will commit funds for an initial two years.[42] Additional funding for the remaining years of the grant will be evaluated at the 18-month period based on progress achieved.

The LFA is an independent entity contracted by the Secretariat to assess the Principal Recipient's capacity to administer funds and provide ongoing oversight and verification of reported data on financial and programmatic progress.

**Call for Proposals:** Funding is based on approved proposals whereby countries are given the opportunity to submit new proposals when the Global Fund announces a call for proposal, also known as "proposal rounds." The timing and frequency of calls for proposals are determined by the Global Fund Board and are subject to resource availability. Once a call for proposals has been launched,[43] countries have approximately three months to respond to calls for proposals. The proposal is developed by the CCM, which is reviewed by an independent body called the TRP. The Global Fund Board makes a decision to grant funds on the basis of the goals, activities, and targets set out in the proposal and on the basis of the TRP recommendation to the Board that the proposal has technical merits.

## B. GAVI and Global Fund on Performance Verification and DQAs

GAVI put in place DQAs early in the inception of the programmes. However, the Global Fund's rapid start-up and external pressure to approve and implement programmes did not allow for the development of an M&E framework or DQAs within the Global Fund grant programmes. The DQAs and tools were developed jointly with partners only at the time of the first year of Phase 2 grants by the M&E team. One of the main reasons was due to the late start-up of the M&E team.

GAVI selected certain areas (which meant a better focus on quality assurance processes) versus the Global Fund where programme implementation varied from selected provinces to country-wide scale up implementation efforts.

Unlike GAVI, there were no main criteria or guidelines set up by the Global Fund for the LFAs to conduct "routine" implementation verification at the sub-recipient level. In the early days of the Global Fund, accountability was held at the PR level only and sub-

[42] Although the approved proposal will be up to five years.
[43] Announcements are normally made via press releases, web postings and at Global Fund Regional Meetings.

recipient verification decisions were left to individual Fund Portfolio Managers as to how the Global Fund engaged the LFA's time in the verification process. In addition, FPMs were under internal pressure to keep the LFA cost down. DQA issues were overlooked early on with Global Fund grants. Performance-based funding utilised by the Global Fund was seen as an important measure at a policy level but lacked rigorous standards of implementation at the operational level.

In the early stages of the Global Fund, the LFA's knowledge to conduct performance verifications particularly on the programmatic component was found to be weak. The LFAs were able to do data verification for process and output indicators but lack the technical knowledge and expertise to link much more complex outcome and impact level indicators to performance-based funding in order to determine disbursement recommendations. Subsequently, the LFAs outsourced and utilised M&E experts in order to improve verification processes for the Global Fund.

## C. Organisational Analysis

The Global Fund's organisational structure was built on the experience of other existing initiatives, such as GAVI, the Global Environmental Facility (GEF), other global partnerships (e.g. Roll Back Malaria, Stop TB), and the International Partnership against AIDS in Africa. It brings together a new public-private partnership comprised of multilateral and bilateral donors, disease affected countries, civil society and the private sector.

The blueprint of the Global Fund can be seen most closely in GAVI. The table below outlined by Murphy to describe the Politics, Management Operations and Support model for GAVI, has been utilised to show close linkages across the functional and structural elements between GAVI and Global Fund and more recently with GAIN.

**Table 1: Politics, Management, Operations and Support**

| Functional clusters | Principal Activities | Structural Elements | | |
|---|---|---|---|---|
| | | GAVI | GFATM | GAIN |
| **Politics** | High policy and strategy | GAVI Board | GFATM Board | **GAIN Board** |
| **Management** | High executive authority | GAVI Secretariat | GFATM Secretariat | GAIN Secretariat |
| | High strategic planning | Working Groups | Board Sub-Committee Working Groups | |
| **Operations** | High technical expertise (regional-country) | Regional Working Groups | In-country Partners | In-country Partners |
| | Coordination | Intra-agency-Coordinating Committee (ICC) | County Coordinating Mechanism (CCM) | National Fortification Alliance |
| | Oversight Role | Data Quality Auditors | Local Fund Agents (LFA) | In-country Advisors |
| **Support** | High problem solving | Task Forces | | |
| | High expertise for assessment | Independent Review Panel | Technical Review Panel | Proposal Review Panel |
| | Technical review | | Technical Evaluation and Reference Group (TERG) | |

Source: Adapted from Murphy, 2002

All three organisations have a high-level policy making body (the Boards), the Secretariats for management and support of the Boards and independent review bodies for the proposal review and recommendation process. At the operational level, monitoring and oversight is done by regional working groups, CCMs and in-country partners as well as outsourced entities such as the data quality auditors and Local Fund Agents.

The Global Fund's organisational design in 2002 was based on a matrix organisation model, which incorporates dual responsibilities and reporting relationships. It takes the functional approach grouping people into departments or sub-units based on similar skills, expertise and functions performed.[44] Such a structure is best suited for small organisations (e.g. GAVI, GAIN or the Global Fund). The matrix design is well reflected in the organogram of the Global Fund in Figure 1 (e.g. operations team, portfolio team, strategy and evaluation team, and external relations team).

[44] Cook and Hunsaker, 2001 p. 88

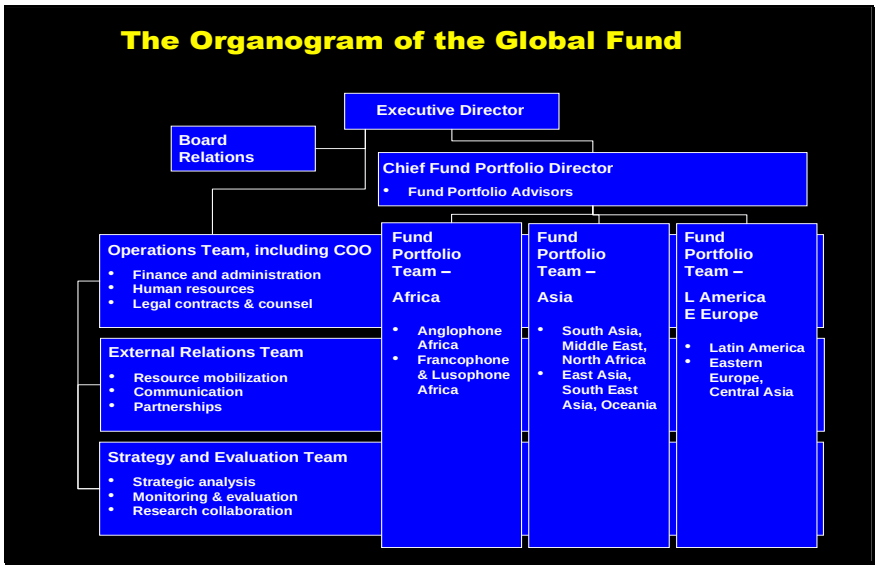


Fig. 1: Global Fund Organogram. Source: The Global Fund 2002.

However, within a short period, the organisational structure of the Global Fund has undergone several changes. For example, the initial organogram consisted of 2 FPMs for each of the three regions (Asia, Africa, Eastern Europe and Latin America) and a total Secretariat staff of approximately 40 people. Within one year, the Global Fund has expanded to 75 staff to cope with the demands and increasing workload. By October 2006, the staff expanded to 250. The expansion of staff and organisational needs resulted in a major restructuring of the Global Fund Secretariat particularly in the portfolio and grant management areas. Under operations, portfolio teams were grouped into eight clusters including the formation of two new units: operational partnerships and country support and portfolio services and policy unit.

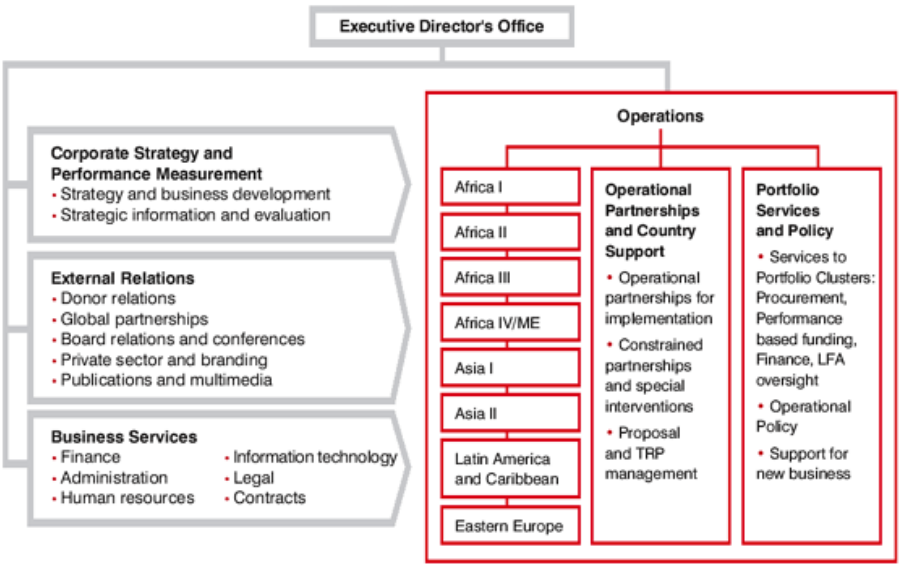

**Figure 2. Global Fund Organogram, 2004**

### a. Analytical Framework:

The Global Fund organisation system can be described as a young dynamic system, which is defined as any system, that changes overtime as structures and functions adapt to external disturbances and conditions.[45] This dynamic system compliments the framework of a Learning Organisation, popularized by Peter Senge of Organisation Learning Centre at the Massachusetts Institute of Technology (MIT). It is defined as a deliberate effort by organisational members to develop models, tools and techniques for their organisation to change and grow faster than competitors.[46]

### b. Learning Organisation:

According to Peter Senge, there are five characteristics of Learning Organisations,[47] which include:

**Systems Thinking:** members perceived their organisation as a system of interrelated processes, activities, functions and interactions. Any action taken will have repercussions on the other variables in the system. It is therefore important to see the entire picture in the short and long run.

**Shared Vision:** described as belief and commitment toward a goal deeply desired by all. Sublimation of competing departmental and personal interests for the achievement of the shared vision (this vision of the Global Fund shared across many stakeholders including donors, country, multilaterals, bilaterals, NGOs and Civil Society to accelerate efforts to fight the three diseases.

**Personal Mastery:** continual learning and personal growth by all organisational members. Individuals are willing to give up old ways of thinking and behaving to try out possible better ones for themselves and organisation.

**Mental Process Models:** shared internal image of how individuals, the organisation, and the world work. Willingness to reflect on the reasoning underlying our actions and to

[45] Cook and Hunsaker, 2001, p. 13.
[46] Cook and Hunsaker, 2001, p. 551.
[47] Cook and Hunsaker, 2001, p. 551.

change these assumptions when necessary to create a more appropriate process for doing things.

**Team Learning:** organisation members opening communicate across departmental and hierarchical boundaries to help all members solve problems and learn from each other thereby decreasing the need for personal wins in order to increase the search for the truth for the good of the entire team.

Organisations have different learning techniques. Among the four types of organisation learning, competitive acquisition, experimentation, continuous improvement, boundary sharing,[48] the Global Fund exercised the **experimentation** and **continuous improvement** models. Experimentation is defined as a learning process to generate new ideas. The Global Fund was striving to implement various experimental models focused on innovation including result-based disbursement or performance-based funding approach,[49] by its lean grant management and flexible funding approach with procurement guidelines; flexibility in appointing multiple PRs; and harmonisation of funding procedures to simplify donor fund flows.

Continuous improvement attempts to master each step in the process before moving on to the next with a goal to become the technical leader for a process or product. The Global Fund to date has proven to be a flexible organisation continuously learning based on its existing knowledge and using this knowledge to improve its processes. This can be seen in the improvements made in the process area of the Global Fund (e.g. proposal guidelines, an introduction of internal appeals process, streamlining results-based disbursement forms, flexibility with tax and tariff issues etc.).

Specific actions for learning organisational include: establishment of a learning strategy with an explicit a strategic intent to learn. This includes a commitment to experiment, a willingness to learn, and a willingness to implement the necessary changes for continuous improvement. This learning strategy can be seen in Section V in the description of steps and processes to change policies and procedures to improve practices.

[48] Cook and Hunsaker, 2001, p. 552.
[49] Performance-based funding has been employed by various technical and donor agencies, e.g. USAID, CIDA and other NGOs for certain projects but has not been implemented on a large scale.

The other action is the modification of organisational culture where optimal learning can occur within a culture that encourages experimentation, trust and risk taking, and values growth openness. Organisations also need to learn from past mistakes and to be able to bring issues forward for dialogue and discussion. This concept is also described in Cook and Hunsaker as “regenerative interaction” helping each other grow towards mutual cooperation and in promoting constant growth and improvement.[50]

This regenerative interaction can be witnessed within the organisational culture of the Global Fund which fosters different FPMs to be autonomous and are encouraged to be solution oriented. This is especially applicable at country level where portfolio managers are placed in a position to assess the situation and to do what is 'right' for the grant management and implementation arrangements. This culture is necessary for FPMs to bring in on-time delivery of grant agreements with rapid disbursement of funds and in facilitating that results can be achieved at country level. Within Team learning and Personal Mastery, consideration is given to lessons learned from the field for improving current policies and practices (e.g. streamlining the PR's work plans and reporting requirements). This approach of encouraging self-expression and individuality among managers is defined as “management by ideology” or a system of information management based on trust in individual managers to be sensitive to the attitudes and perceptions of all participants in a decision-making situation and to do what is best for all by applying appropriate values and beliefs.[51]

As a young dynamic organisation, the driving forces for the Global Fund are numerous, ranging from external pressure to sign grants and making rapid disbursements while policies and procedures were still under development (one of the restraining forces outlined in the model). Other restraining factors range from shortage of time, unclear procedures (based on evolving processes) to country capacity. Although some processes can be solved within a given timeframe, other elements such as country capacity are a longer-term systemic issue may not be easily resolved. The challenges of systemic issues are outlined in later chapters related to ACT reprogramming and implementation activities.

[50] Cook and Hunsaker, 2001 p. 320.
[51] Cook and Hunsaker, 2001 p. 60

## SECTION III: RESEEARCH METHODOLOGY

### A. Introduction

The thesis in this dissertation presents an organisational and policy analysis of the Global Fund focusing on the period from its inception in 2002 to 2007. It documents processes of change, developments, and debates in a rapidly growing institution. Specifically, the study provides an in-depth examination of the trends of the Global Fund's performance-based funding approach over this five-year period. The literature review includes an examination of practices and approaches to date - from concept (its origins and rationale), to its implementation on a global scale, including assessment of its impact on end-user behaviour.

Several theoretical frameworks were used for analysis, which is based on the Learning Organisation model of Peter Senge[52] and frameworks of other learning organisation theorists (e.g. Hiddling and Catterall, Gavin, Jensen, Rowden etc.) in order to analyse contributing factors for the evaluation of alternative approaches to promote positive changes. Peter Senge describes the Learning Organisation in terms of Systems Thinking; Shared Vision; Personal Mastery; Mental Process Models; and Team Learning – all of the characteristics, which can be witnessed in the internal workings of the Global Fund (refer to Table 2).

According to Tsang (1997), it is important to note the difference between organisational learning and a learning organisation. In organisational learning, the former describes types of activity that takes place in an organisation while the learning organisation refers to a particular type of organisation in and of itself. The more important distinction is that a learning organisation is one, which is good at organisational learning.[53] Hidding & Catterall (1998) describes learning as a process of acquiring new skills or knowledge resulting in a different behaviour. Learning can be directed and managed. Learning occurs in individual, teams, departments and overall or organisation as a while when mental models at an individual level become shared among other individuals, teams,

[52] , and the theory and practices of the learning organisation. http://www.infed.org/thinkers/senge.htm
[53] Tsang, 1997, p.75

departments or organisations.[54] This is similar to the team learning approach described by Peter Senge.

Rowden (2001) provides four defining characteristics of the learning organisation: 1) constant readiness; 2) continuous planning; 3) improvised implementation; and, 4) action learning.[55] Constant readiness consists of perpetual state of preparedness for change since, amid highly turbulent conditions; the organisation needs to be equipped to deal with anything and to re-evaluate past assumptions and future directions. Continuous planning pays attention to open, flexible plans that are fully shared and embraced by the organisation versus a rigid or fixed-planning process. Improvised implementation is part of a learning organisation and encouraging experimentation, rewarding small wins and institutionalising success throughout the organisation.[56]

Nevis, Ghoreishi and Gould (1995) point out that learning does not always occur in a linear fashion and that learning may take place in informal or unintended ways. Therefore, there is a need to shift emphasis to look for a more fluid and chaotic learning environment, seeking less-defined, more subtle embodiments.[57] Learning organisations do not wait for problems to emerge; rather reflection becomes part of the way business is done. Through this process, the original assumptions are questioned and the need to search for deep system (double loop) solutions to problems.[58] Jensen (2005) describes double-loop learning as learning that results in a change in the values of the theory-in-use, as well as in its strategies and assumptions.[59] It includes a kind of leaning where norms and routines are changed, where the values guiding the existing context and strategies are questioned and assumptions are under consideration.[60]

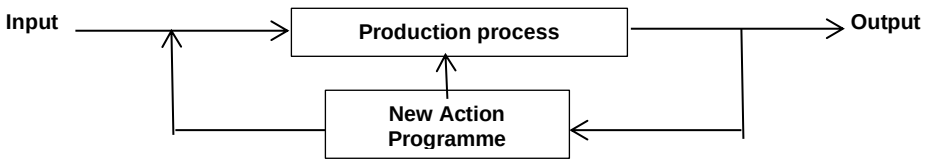


Figure 3. Double-loop learning, Jensen 2005

[54] Hidding & Catterall, 1998, p.5
[55] Rowden, 2001, p. 15
[56] Ibid., p. 16
[57] Nevis, Ghoreishi and Gould,1995, p. 4
[58] Rowden, 2001, p. 16
[59] Argyris & Schon, 1996, p. 20
[60] Jensen, 2005, p. 57

For this paper, several types of qualitative methodology were applied: 1) Participant Observation Theory (in particular through extended participation) and the concept of Positionality; and 2) Narration with chronological and non-chronological dimensions; and, 3) Reflective/reflexive empirical research methodology (e.g. Bourdieu and Wacquant (1992). The findings generated from this analysis process are focused so that they inform key areas of the public health literature and its associated professional practice, as well as provide insights into academic discourse interested in learning, knowledge and innovation.

**1. Participant Observation:** Participant observation is historically rooted in anthropology and ethnology as well as in the nineteenth and twentieth century social reform movements in the US and the UK. In the early 1960s, methodological interest focused on systematic rationalisation and the development of processes as an independent sociological research method. Participant observation was seen as an important route to sociological accounts to nurture the growth of methodological approach for research. Lüder (2004) points out some important aspects in participant observation; in particular, the participant observer and their relations in and to their field. In methodological terms, the participant observer is compelled to adhere to scientific standards as distant, impartial observers but at the same time is required to act in a socially and culturally acceptable way within a particular context or situation, requiring the participant observer to be detached and be personally involved at the same time. However, Lüder (2004) also noted that experience gained from this process is crucial because it can provide helpful insights as to the structure and object of the investigation. Participation over an extended period of time (**extended participation**), which entails a lasting co-presence of observer and the events,[61] was seen as a challenge for ethnographers having to balance with delicacy, observation and distance. It was recognised that too rigid adherence to the principles of methodological procedure could block or hinder access to important information and that a more flexible use of different methodological approaches was required to adapt to the situational context. Hammersley and Atkinson (1983) captured the concept as “the ethnographer participates, overtly or covertly, in people’s daily lives for an extended period of time, watching what happens, listening to what is said, asking questions; in fact, collecting whatever data are available to throw light on the issues with which he or she is concerned”.

[61] Amann and Hirschauer, 1997, p. 21

Walt et al. (2009) points out one of the challenges of doing health policy analysis is how a researcher is viewed or 'situated' as this is critical to their ability to access the policy environment and conduct meaningful research, especially in environments that require engagement of policy elites, and dealing with sensitive political issues. They note that policy analysis literature seldom explicitly discusses researcher **'positionality'** and its possible impact on the research process. The **positionality** distinction is made between 'insiders' and 'outsiders', where the former may be both participants and researchers (i.e. participant observers) of the policy process. In seeking to unravel complex policy dynamics, insider s may see things quite differently to outsiders with implications for the data collected and the interpretation of research findings.[62] This view is reinforced by Merriam et al. (2001) "… being an insider means easy access, the ability to ask more meaningful questions, read non-verbal clues, and most importantly, to be able to project a more truthful, authentic understanding of the culture under study".[63]

**2. Narration:** Martin & Bauer (2007) describes narrative accounts as rich in indexical statements - referring to personal experience, and focusing on events and actions.[64] Schütze (1999) and Bruner (1990) denoted as "narration reconstructs actions and context in the most adequate way; it reveals place, time, motivation and the actions".[65]

Narration provides context, which outlines sequential events leading to an end point. Yin (2009) refers to narration as 'constructive validity'; a selection of specific measures – discusses shortcomings using multiple sources of evidence; establish a chain of evidence. It is in essence an evaluation leading to outcomes including learning outcomes.[66] Similarly, Ricoeur (1980) describes narration or story telling as the number of actions and experience into a sequence. Within the actions, is the number of characters (i.e. change agents or learning agents) which brings about situational change bringing into light those elements which were previously implicit.[67] There are two dimensions of storytelling: 1) a chronological dimension (i.e. reference to narratives as a sequence of episodes); and 2) non chronological dimension (involving construction of a whole from successive events or configuration of a plot). The non-chronological aspect of a narrative explains the reasons found behind the events, criteria for selection, value

[62] Walt et al. 2009, p. 114
[63] Merriam et al. 2001, p. 411
[64] Martin W., Bauer, 2007 p. 57
[65] Schütze 1999 and Bruner, 1990, p. 558
[66] Yin, R.K., 2009, pp.40-41
[67] Ricoeur, 1980, p. 58

judgement attached to the narratives and to all the operations of the plot.[68] A plot can be defined as a construct of small stories within a big story, reflecting the research design for embedded multiple units of analysis.

A narrative goes beyond listing of events but an attempt to link them both in a specific time period and in meaning. The story allows for the production of meaning or the operation of a plot, which provides coherence and meaning to the narrative and context in which we understand each of the events, actors, description, goals, motivations and relationships that usually form a story. A narrative goes beyond the chronological sequence of events to recognise its non-chronological dimensions expressed by the functions and meanings of the plot.[69]

**3. Reflective/reflexive empirical research** is one of the qualitative methodologies which places the researcher at the centre of the research to reflect on several levels or directed at several themes. Yin (2009) describes this approach as 'internal validity', which is a main concern for explanatory case studies and broader application of making references.[70]

According to Bourdieu and Wacquant (1992), there are different varieties of reflexivity; one of which is where the researcher is seen as being inserted into a social field, with specific relationships of competitions and power conditions generating a particular 'habitus', that is, a pattern of action dispositions, among the participants – also belongs here.[71] Alvesson & Sköldberg (2009) describes reflective research with two basic characteristics: careful **interpretation** and **reflection**. The former implies that all references (whether it is considered trivial or non-trivial) to empirical data are the results of interpretation and therefore Alvesson & Sköldberg emphasised that interpretation calls for the utmost awareness of the theoretical assumptions and the importance of language, are major determinants of interpretation. The latter 'reflection' turns attention inwards towards the researcher, the research community, the society, intellectual and cultural traditions as well as the nature of the problem, and narrative in the research context. Reflection refers to a continuous consideration for various basic dimensions and in the process of interpretation. **Systematic reflection** at several different levels (e.g. embedded multiple units of analysis) can provide quality towards interpretation for

[68] Martin W., Bauer, 2007 p. 71
[69] Martin W., Bauer, 2007 p. 59
[70] Yin, R.K., 2009 pp. 40-41
[71] Alvesson & Sköldberg, 2009, p. 5

empirical research. Alvesson and Sköldberg (2009) sums the reflective process as one that "constitutes a re-construction of the social reality in which researches both interact with the agents researched and, actively interpreting, continually create images for themselves and for others, images which selectively highlight certain claims as to how conditions and processes, experiences, situations, relations – can be understood, thus suppressing alternative interpretations".[72] Similarly, Hammersley and Atkinson (1983) stated the importance of the ability to penetrate reflexively on one's own action, experience and observations in the field, coupled with one's own individual, cultural, social and existential assumptions which therefore becomes the ethnographer's decisive competence.

## B. Literature Review Strategy

Literature search construction identified major concepts, topics, and terms from selected research questions broken down into concepts (e.g. performance-based funding, result-based funding, global health initiatives, global health, health systems strengthening). Synonyms and subject headings were identified for the search statements using keyword search, Boolean searches, and changed the approaches as required. The following bibliographic databases were searched: MEDLINE; PubMed; Web of Science; Cochrane; Google; Google scholar; Social Science and University websites. Associations, organisations and government web sites were also searched (e.g. WHO, CDC, US Congressional Research Service, USAID, GAVI, GAIN, DFID) for related articles. Additional research articles were identified by reviewing reference lists of all articles that were included in the paper and a evaluating publicly available documents. A practical screening criterion was applied to the searches for studies and literature from 1990 for articles published in English language.

External sources for related articles including online library catalogues, journals, periodicals, research publications and other meeting proceedings. In addition, internal sources of data were also utilised including: Secretariat and country-level work experience; attendance and observation at Board meetings; participation and attendance of regional and other partnership meetings; stakeholder meetings at headquarter and country levels; and other presentation materials.

[72] Ibid., p. 6

## C. Research Methodology

The research design for the malaria reprogramming study is mixed-method involving both quantitative and qualitative methodology. Interviews and participant-observation methodologies were utilised to document the organisational study as it unfolded and as a strategy to capture the "emergent" nature of the research. At the time the study was undertaken, there were limited data and literature sources on the performance-based funding approach especially in the public health and global health field.

## D. Justification for methodology

Case study research methodology was applied for this research in order that the research can be based on real world occurrences rather than based on normative models. The case study approach was adopted as an appropriate method for investigating the dynamic relationships between evolving scientific evidence and the application of performance-based funding instruments.

By combining data analysis methods of quantitative and qualitative research approaches, and by utilising a mixed methods approach, the researcher is able to design a single research study that encompasses the complex nature of events from the participant point of view as well as the relationship between measurable variables. Triangulation and complementarity can be achieved drawing from multiple sources of quantitative and the qualitative data and approaches to the research study.

Extended participant observation, positionality, narration, and reflexive empirical research methodologies were selected to increased internal validity (credibility), external validity (transferability) of the study. Internal validity can be achieved through triangulation, positionality and reflexive research methods to help clarify researcher's biases, assumptions and worldview at the beginning of the study. Internal validity can also be conducted through feedback loops (Jensen 2005), from multiple windows of reality and multiple levels of analysis from findings and data collected. External validity can be measured through extended observation and narration to validate the extent to which it is generalisable to different times and settings.

Extended participant observation as described by Hammersley & Atkinson involves the process of registering, interpreting and recording influenced by continuous observer-observant translation over a period of time. The observer can directly witness actions and events avoiding the need for individuals and their willingness to provide information.

Extended participant observation was used since I was in a unique position to engage in extended participatory approach to observe events, make notes of various meetings, making mental notes of participants and their reactions over the course of the study. As a participant-observer, I was able to witness and document the events related to the malaria reprogramming process which took place within the five-year period. The data was gathered in a systematic way, which formed the basis of a practiced-based analysis using a well-established theoretical lens from organisation studies such as Peter Senge's Learning Organisation (Table 2).

Extended participant observation methodology[73] was also utilised in order to record and analyse how countries reached a decision to transition to ACT and the challenges encountered. It provided me with the opportunity to be an impartial observer but also to be detached and personally involved at the same time.

This 'positionality' provided me with the unique opportunity to reflect on actions, experiences and field observations coupled with social and cultural assumptions and the unique insider perspective also provided me with the ability to be able to "project a more truthful, authentic understanding of the culture under study" (Merriam et al. 2001); and thereby increase validity of the research.

Martin & Bauer denoted that narration provides context based on a chain of evidence which supports construct validity and ascertains whether operational variables adequately represent theoretical constructs. For the research on malaria reprogramming, I followed events chronologically over a five-year period, observing and recording a sequence of events from the publication of the Lancet article (i.e. the beginning or the origination of the story) to the outcome of countries which went through malaria reprogramming (i.e. the end point or the learning outcome as seen through the Learning Organisation lens) as an attempt to link time and the main events. I was also able to put together non-chronological construction of a 'whole' or complete picture from

[73] Participant observation is a form of subjective sociology, with the aim is to understand the social world from the subject's point-of-view.

successive events; from the time international pressure emerged in 2004 calling for a rapid change to ACTs, to the drug policy change process of countries, the global supply and demand side issues, partner coordination and technical support process, country ownership and related operational issues, review of performance of grants and the resulting policy implications related to a shift in scientific evidence and performance-based funding.

Reflexive empirical research placed the author at the centre of research allowing for free interpretations and reflections. Systematic reflection at various levels through the lens of learning organisations, i.e. examining the global, secretariat, and country levels, linking this information with embedded multiple unit analysis provided an in-depth picture of the research from studying consistent patterns of data across the units for interpretation.

Given that social interaction component of interviewer-interviewee relationship can be skewed towards asymmetric relationships within reflexivity, the act of reflection allowed me to pay special attention to asymmetric relations in this study. This includes considerations for, but not limited to: the interviewer's institutional affiliation at the time of study; uneven or asymmetric power relationship between donor and recipient countries; political sensitivities; and uncertain environment of ACT reprogramming. By using these methods, I was able to capture multiple windows of reality and make linkages derived from systematic reflection (e.g. embedded multiple units of analysis) in order to reduce bias and increase internal and external validity.

### E. Qualitative Research Method

As mentioned above, the research design utilises embedded multiple units of analysis, which could be utilised within a single case design or within an embedded design. Yin (1994) cites that a research study may include the main as well as smaller units on different levels striving to look for consistent patterns of evidence across units but within the same case design.[74]

[74] Yin, R.K., 1994 p. 3

| Exploring Senge's proposition | Focus | Level of Analysis |
|---|---|---|
| When organisations are in situations of rapid growth and change, only those that are flexible, adaptive and productive will excel and achieve its mission and objectives. | Senge's Five disciplines of the Learning Organisation:<br>➢ Systems Thinking<br>➢ Personal Mastery<br>➢ Mental Models<br>➢ Building a shared vision<br>➢ Team learning<br>Jensen<br>➢ Double loop learning<br>Rowden<br>➢ Constant readiness<br>➢ Continuous planning<br>➢ Improvised implementation<br>➢ Action learning | Applied to an organisational level analysis at three levels:<br>➢ Global Level (Board, Partnerships)<br>➢ Secretariat Level<br>➢ Country Level |

Table: 2 Summary of Analytical Approach

For this study, Peter Senge's learning organisation framework is examined within the lens of reflexive empirical research, i.e. systematic reflection is made in the form of embedded analysis as outlined in Table 2 to provide quality for interpretation of empirical research.

The table below outlines how the different levels are applied through the various Learning Organisation frameworks. The research looks at the evolving framework of operational policies of the Global Fund, which describes efforts to improve the output and quality of an organisation and its performance and practices with a focus on three levels: a) at the Global level by examining Global partnerships and issues related to coordination of ACT production and supply at the global level; b) at the Global Fund Secretariat level by examining the organisational structure, decision-making process as well as performance of PRs; and c) at the country level by examining coordination and implementation challenges.

| Unit of Analysis | Focus | Examined through the Lens of Learning Organisations |
|---|---|---|
| Global Level<br>Global Fund Board<br>Global Partnerships | ➢ Board policy changes<br>➢ Partnership support/environment | ➢ Senge (Systems Thinking, Personal Mastery, Mental Models, Building a shared vision, Team learning)<br>➢ Jensen (Double loop learning)<br>➢ Rowden (constant readiness, continuous planning, improvised implementation, action learning) |
| Secretariat Level | ➢ Development of new policies<br>➢ Changes in organisational structure<br>➢ Coordination with partners<br>➢ Decision-making process<br>➢ Communication with countries | ➢ Senge (Systems Thinking, Personal Mastery, Mental Models, Building a shared vision, Team learning)<br>➢ Jensen (Double loop learning)<br>➢ Rowden (constant readiness, continuous planning, improvised implementation, action learning) |
| Country Level | ➢ Changes to proposal guideline process<br>➢ Grant signing process<br>➢ Principle Recipient Arrangements<br>➢ Fiduciary and programmatic management process<br>➢ Coordination and Implementation Challenges | ➢ Senge (Systems Thinking, Personal Mastery, Mental Models, Building a shared vision, Team learning)<br>➢ Jensen (Double loop learning)<br>➢ Rowden (constant readiness, continuous planning, improvised implementation, action learning) |

Table 3. Summary of Unit Analysis within Learning Organisational Framework

The linkages of the various elements of the qualitative methodology to the chosen research design of embedded multiple units of analysis[75] is outlined below:

| Authors | Qualitative Methodology | | Research Design |
|---|---|---|---|
| Baurer, Bourdieu & Wacquant<br>Alvesson<br>Skoldberg | Reflective/reflexive empirical research<br>Systematic reflection at different levels | | Embedded Multiple Units of Analysis |
| Luder<br>Hammersley & Atkinson<br>Walt, G. | Participant Observation Theory (extended participation)<br>Internal validity<br>Positionality | | |
| Martin & Baurer<br>Schütze<br>Bruner | Narration<br>chronological<br>non-chronological dimensions<br>configuration of a plot | | |

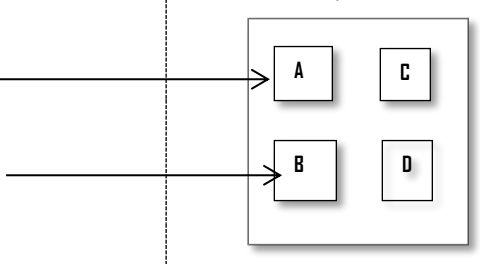


Table 4. Linkages to Embedded Multiple Units of Analysis

[75] Unit of analysis is the actual source of information (e.g. information from an individual or an organisational document).

## F. Goal and objectives:

The goal of the research was partly to analyse the extent to which the outcomes reflect the Learning Organisation Framework. The aim of the study is to develop a better understanding of the performance-based funding approach of the Global Fund and to examine its response to rapid change in treatment policies. Outcome of the study will reflect the 'thinking' through the lens of Learning Organisations.

Contribution to practice would be to generate insights and suggestions on how the Global Fund could move forward the Learning Organisation Principles – improving organisational process and outcomes through a more effective learning process.

The main objectives of the research were to:

- gain a better understanding and insight into challenges and constraints of the Global Fund by examining the organisational structure and mechanisms related to performance-based funding approach;
- review and analyse key achievements of performance-based funding to date;
- review and analyse reprogramming of ACT as an example of performance-based funding;
- make appropriate recommendations to improve effectiveness of significant reprogramming[76] within the performance-based funding approach for the Global Fund; and,
- reflect on the findings using the principles of the learning organisations.

The main research questions are based on:

1. What are the different methodologies and criteria for performance in performance-based funding approaches?
2. How is the Global Fund doing Performance-based Funding within the context of reprogramming?
3. What are the key constraints and challenges of reprogramming?
4. What are the consequences of major reprogramming efforts such as the switch to ACTs?

[76] Significant reprogramming is defined as a change this is sufficiently substantive that questions the original intent of the approved proposal by the Technical Review Panel.

5. What is the system-wide effects of such reprogramming efforts?
6. What are the major lessons learned from this type of performance-based funding approach?

### G. Semi-structured Interview Process:

Semi-structured interviews were conducted for the study in order to obtain a deeper understanding of the responses. Semi-structured interviews follow an open and informal interview process where interviewers are able to ask follow-up questions based on interviewee response to obtain a more comprehensive picture.

One on one interviews were conducted by phone and email with in-house team members involved in malaria programmes and ACT reprogramming including FPMs on the form of structured and semi-structured interviews. Interview data was gathered to gain insight on PBF approaches, the background, usage and lessons learned. It also provided an opportunity to obtain rich data and gain insights into the interviewee's perception and values.

The selection process for FPMs was based on countries undergoing malaria reprogramming with 27 FPMs[77] which include a total of 26 countries with 2 FPMs assigned for Sudan (North and South Sudan). Phone interviews were conducted between 2005-2006, one year after the reprogramming initiative (refer to Annex 10). The purpose of this phase of the research was two-fold. The researcher made contact with the interviewees (by telephone and email) to seek clarification and other details on the topic following the interview process. The data obtained provided contextual information to identify the process, challenges, constraints and outcomes of reprogramming. The contextual information also provided a valuable supplement to the quantitative analysis process undertaken (e.g. grant score cards, and grant performance reports) for Phase 2 renewal decisions for funding. Questions for FPMs were the following:

1. Can you provide a progress update on the malaria programming grants in your portfolio?
2. What were some of the challenges that countries encountered?
3. What is the current policy development?

[77] A total of 26 countries including N. and S. Sudan. There are 2 FPMs for Sudan.

4. Was ACT approved in the treatment guidelines?
5. Did country (x) switch to ACTs? Why or why not?
6. Is there a quantification process at country level?
7. What were the reasons that affected performance of malaria grants?

## H. Ethical Considerations

The research was based on open access materials available at the time of research. As part of data collection efforts, the information from the interview process served to fill the gaps and to supplement information gathered from the open access materials. The focus of the study was primarily to reflect on the organisational analysis of a learning organisation, and not on individual behaviour. Since no personal information of any kind was involved, including personal opinions, it was considered that written consent was not warranted.

For the internal interview process, institutional permission was sought and informed consent was requested by email/phone at the beginning of each interview. Privacy, confidentiality and anonymity was maintained by removing any identifying descriptions prior to dissemination of information. The internal interviews served to gather an account of historical facts on malaria grants how grant management issues were handled.

In order to minimise bias and the effects of asymmetric relationships between the insider position of the researcher and the countries, focused group discussions were not conducted whilst acknowledging that this could have facilitated further validation of the identified issues.

This thesis was carried out as an internal evaluation within the Global Fund (GF), commissioned by senior GF management. The aim was to learn institutional lessons from a challenging episode in the early history of the GF. The approach was to focus on the organisational analysis of a learning organisation, and not on individual behaviour.

The evidence was collected primarily from open-access written materials, mostly GF documents. These were supplemented by interviews with GF staff. These interviews concerned historical facts (rather than the views of staff), and were used to confirm and to fill in the factual gaps in the documentary evidence, for example on what happened in the management of malaria grants.

For the internal interview process, institutional permission was sought and informed consent was requested by email/phone at the beginning of each interview. Privacy, confidentiality and anonymity was maintained by removing any identifying descriptions prior to dissemination of information. The internal interviews served to gather an account of were handled.

Since the work was an internal GF evaluation, and the data-collection methods included no personal opinions and no personal information of any kind, the Supervisory Committee at the time (2003-4) did not consider it necessary to seek formal ethical approval. This decision was later reviewed by the chair of the LSHTM ethical research committee. His specific comment was "We would today expect ethics approval for the 27 phone interviews of country directors. However, these were conducted in 2006-7 when we were less rigorous about these matters. The interviews did not contain any personal information, nor apparently any opinions, so presumably are entirely factual. We do not feel that anybody could have been harmed or misled in this study and no egregious ethical missteps have been made."

In order to minimise bias and the effects of asymmetric relationships between the insider position of the researcher and the countries, focused group discussions were not conducted whilst acknowledging that this could have facilitated further validation of the identified issues.

## I. Strengths and Weaknesses of Semi-structured Interviews

The strengths of semi-structured interviews are based on the depth of information. The question guide outlines the main list of questions for each interview process. The order for the list of questions was not set, which allowed interviewees to respond freely and to share their views, which could lead to higher data validity. Interviewees were probed with follow-up questions to gain a better understanding of their views and perspectives, and to be able to discuss complex situations which may arise from the interview process.

The weaknesses of semi-structured interviews include the skill of the interviewers and their ability to probe the interviewees without bias or being judgmental. The information collected and produced from the semi-structured interviews might not be generalisable to other settings, as they are based on interviews with a limited number of participants.

## J. Strengths and Weaknesses of Qualitative Research

Qualitative research can be helpful with in-depth analysis and in describing complex situations seen as suitable for some case studies. It provides an insider's perspective and understanding of the situation embedded within a local context.

The research examined changing and dynamic processes (documenting sequential patterns and change) and used qualitative methods of positionality, narration (chronological and non-chronological dimensions of events), and reflexive empirical research to generate a descriptive model related to the event. Data was collected to respond to changes which occurred during the course of the study period.

Qualitative research and data collection and analysis can be extensive compared to quantitative research methods. The results can also be influenced by the interviewer's positionality which could lead to personal biases in qualitative analysis. The researcher's presence during data collection could also be affected by the interviewee's responses.

## K. Data Analysis

Qualitative data include notes of semi-structured interviews, minutes of the meeting, notes and key statements from phone interviews and face-to-face meetings, observations and internal interview records.

As it was a small-scale survey, the results were hand tallied. Computer analysis was not used due to the fact that the questionnaire was short and the number of respondents was fewer than fifty. Data was sorted and ordered based on field notes made for the interviews, research questions and discussion topics. Based on the topics in the question guide, data was converted to analytical notes, which reflect the relation between different factors (e.g. countries which were reluctance to change drug policy) and methodological notes (e.g. follow-up questions or additional information gathered etc.).

Qualitative data was analysed and categorised into problem statements, and identification of issues. Interview data was analysed in different ways, e.g. qualitative statements which describes people's perception associated with drug policy change (either external or internal perception). The contextual information was used for

categorisation in the embedded units of analysis in order to have a better an understanding of performance-based funding environment.

## Q. Quantitative Methodology

Quantitative data which can include a set of open ended or closed questions as variables. For quantitative data, the variables (e.g. grant profiles, country profiles, grant score cards, grant performance etc.) were pre-defined as categorical variables as outlined below.

**Data Collection and review of Global Fund malaria grants:**

For each of the malaria grant approved in Rounds 1 to 3 with a drug component, systematic quantitative data collection and analysis was conducted. Permission for using this data was obtained from the relevant senior project team members. Selection criteria for gathering data on the transition to ACTs were the following:

- Global Fund grants with a malaria component (Rounds 1-3);
- Malaria grants with an anti-malaria drug component;
- Malaria grants already signed with procurement activity;
- Malaria grants signed but with no procurement activity; and,
- Malaria grants that had not signed as yet.

Exclusion criteria include grants, which do not require a transition to ACT:

- Malaria grants where sulfadoxine-pyrimethamine (S/P) has been specified for Intermittent Presumptive Treatment (IPT); and
- Malaria grants where Plasmodium vivax (*P. vivax)* is predominant vector and chloroquine is used for treatment.

A further smaller research study was carried out as part of the malaria grant review process. This is also another example of the embedded multiple units of analysis. The steps undertaken between 2004-2006 are outlined below. Permission for using this data was obtained from the relevant senior project team members.

**Grant Profiles:** For every country with approved malaria grants, the following data was collected: total approved grant funds over the five-year period and grant commitment

over a two-year period; the stage of grant negotiations; the amount of disbursement and expenditure; procurement information including progress towards drug procurement; and estimated treatment coverage over grant lifetime and over the two-year grant commitment period.

**Country Profiles:** Information was gathered on current malaria drug efficacy surveillance data based on 14- and 28-day treatment follow up; other available data based on resistance markers; supplemental information from scientific literature or other research as provided by the authors of the Lancet article and Mèdicins Sans Frontières (MSF); and the current drug policy of the country including information on treatment policy transition and/or change.

**Consultation with key stakeholders:** The Global Fund convened a meeting with the designated representative of the following stakeholders: The Global Fund Secretariat; the Global Fund TRP; WHO; Roll Back Malaria Partnership; authors of the Lancet article; and MSF. The aim of the meeting was to discuss the findings and suggest next steps for country follow-up.

**CCM/Recipient Follow-up through FPMs:** After the consultation meeting, each country was contacted by the Global Fund Secretariat through the CCM and PRs to share the outcome of the analysis and subsequent recommendations and to initiate a process for reprogramming where the need for change in treatment protocol has been indicated.

**Preparations for Round 4:** Country information provided to the TRP was used as a reference in its review of Round 4 applications on 3 – 14 May, 2004.

## R. Data Compilation and Analysis

An initial review of each country's data on drug efficacy vis-à-vis the country's drug treatment policy and protocol was conducted in order to identify gaps and to highlight discrepancies.

Quantitative data was tallied in an excel spreadsheet to facilitate analysis. Simple tables were made with frequency counts[78] for each variable. Some questionnaire data was compiled by hand for answers as well as review of grant profiles, and responses to open-

[78] A frequency count is an enumeration of the number of responses to a specific question.

ended questions. Results of the data analysis (e.g. performance indicators, people reached indicators, and percent of planned targets) are reflected in Tables 8 and 9 of Section VIII for Analysis and Recommendations.

## S. Limitations of the Research

There may be limitations of document review process where information may be unavailable, incomplete or inaccurate especially at a time when Global Health literature was limited. The research design was also limited to a set of issues and a select number of countries (i.e. those countries undergoing malaria reprogramming).

There are limitations with respect to interviewee's response depending on how the interviewer was perceived - "interviewer effect" - which could lead to observer bias. A questionnaire approach was not used at the country level to avoid potential bias from participants responding to their perception and expectation of the Global Fund's performance-based funding approach.

It is acknowledged that as an insider, there might be a role confusion concerning positionality of the researcher, with assumptions and sub-conscious thoughts, potentially leading to unintended negative effects. The insider's position may also be seen as being inherently biased whereas the outsider may have an advantage to ask independent or even taboo questions with the groups being studied.

Limitations also apply to the utilisation of reflexive methodology, particularly if assumptions are taken for granted and overlooking blind spots of the researcher's own social and culture experience, or interactions during the research. Although interpretation may not be value neutral, reflective research methodology does provide a deeper analysis rather than focusing on qualitative data for interpretation.

Whilst reflexivity is important to avoid assumptions, and blind spots, the researcher's affiliation with the institution provided an in-depth organisational knowledge and experience. Within the limits of subjectivity, the act of reflection allowed me to pay special attention to asymmetric relations in this study by conducting the analysis consistent with the organisational objectives within the study period.

There may also be limitations on data analysis where reliance on first impressions may lead to a tendency to ignore diverging information and focusing on data alone may overlook other relevant information.

## SECTION IV: THE GLOBAL FUND

### A. BACKGROUND AND SET UP

The impact of HIV/AIDS and other communicable diseases have intensified over the last decade. More than 62 million people are affected with HIV/AIDS and is the fourth leading cause of mortality worldwide and the leading cause of death in Sub-Saharan Africa.[79] Malaria is a major health burden in Africa, where around 90% of the more than one million deaths from malaria worldwide occur each year constituting 10% of the continent's overall disease burden. Malaria causes at least 300 million cases of acute illness each year, and is the leading cause of deaths in young children.[80] Tuberculosis (TB) kills approximately 2 million people each year. It is estimated that between 2002 and 2020, approximately 100 million people will be newly infected, over 150 million people will get sick, and 36 million will die of TB - if control is not further strengthened. The global TB epidemic is growing and the breakdown in health services, the spread of HIV/AIDS and the emergence of multidrug-resistant TB are contributing factors towards the worsening impact of this disease.[81]

The adoption of Millennium Development Goals (MDGs) by the United National General Assembly (UNGA) in September 2000 focused attention on the need to intensify international development efforts and set targets to reduce poverty and improve heath by 2015. Three of the goals directly relate to health are MDG4 on reducing child mortality, MDG5 on improving maternal health, and MDG6 on combating HIV/AIDS, Tuberculosis and Malaria and other diseases. Since then, other influential initiatives have also called for improved health outcomes, including the Roll Back Malaria Partnership, the GAVI Alliance, Stop TB Partnership, the 3 by 5 Initiative and the Commission for Macroeconomic and Health (CMH). Parallel to these initiatives, there has been a substantial increase in aid funding channelled through various financing mechanisms including the Global Fund.[82] Resources quadrupled between the period of 1990-2007, and the rate of growth accelerated after 2002. The influx of resources included both from the private as well as from the public sectors. The expansion of resources for global health especially in the past 10 years has been accompanied by a major change in the

[79] International Monetary Fund and the World Bank (2003). Development Committee. Progress Report, p. 4
[80] Roll Back Malaria website
[81] World Health Organisation, Tuberculosis Fact Sheet No 104, August 2002
[82] Mangham & Hanson, 2010, p. 86

institutional landscape with the arrival of two new and large channels of resources, (e.g. GAVI and the Global Fund).[83]

In recognition of the growing need to address health and poverty, a series of UN meetings were held including the United Nations Millennium Summit in April 2001, where the UN Secretary General Kofi Annan issued a call for the creation of a funding mechanism, to intensify efforts to address the diseases linked to poverty and to contribute to poverty reduction as part of the MDGs. This was endorsed by world leaders at international meetings (e.g. Summit of Organisation of African Unity or OAU, G8 Summit in Genoa, UN General Assembly Special Session on HIV/AIDS).

In July 2000, the G8 endorse the new AIDS, Tuberculosis and Malaria targets in Okinawa, Japan. In April 2001, the African leaders committed to greater response in Abuja. Two months later in June 2001, at the UN General Assembly Special Session on HIVAIDS (UNGASS) there was an endorsement for the creation of a Global Fund. In July 2001, USD 1.5 billion in pledges was made by the G8 in Genoa, Italy along with the establishment of a transitional working group in Brussels, Belgium in October to conduct the operations of the Fund. In January 2002, the Global Fund Secretariat was created with the First Board Meeting held in Geneva, Switzerland followed by first call for proposals in April 2002. An Executive Director was formally elected in Genoa, Italy to officially assume the role. Hence, the Global Fund to fight AIDS, Tuberculosis and Malaria became operational within one year of its inception.

### Principles of the Global Fund:

Although initiated under a UN umbrella, the Global Fund is an independent, public-private partnership (PPP) with a focus on country ownership and country driven processes designed for responsive, efficient disbursement of funds to countries affected with HIV, Tuberculosis and Malaria.

### Purpose of the Global Fund:

The purpose of the Fund is to attract, manage and disburse additional resources through a new public-private partnership that will make a sustainable and significant contribution

[83] Ravishankar et al 2009, p. 2121

to the reduction of infections, morbidity and mortality, mitigating the impact caused by HIV/AIDS, tuberculosis and malaria in affected countries, and thereby contributing to poverty reduction as part of the Millennium Development goals.[84] The process to attract, manage and disburse funds to achieve impact has been translated into the mandate of the Global Fund: raise it (resource mobilisation); spend it (portfolio management, grant agreement and disbursements); and prove it (i.e. disbursement of funds are achieving results at country level).

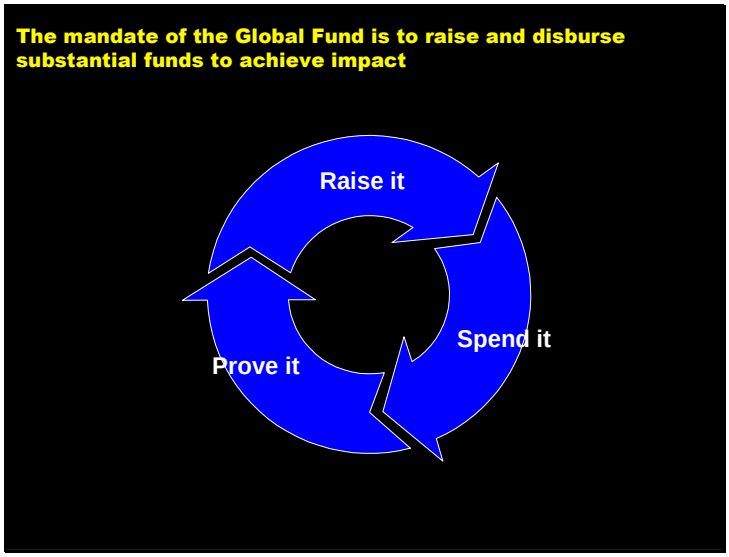


**Fig. 3: The Global Fund Mandate. Source: The Global Fund 2002**

## Resource Mobilisation:

In the establishment of the Global Fund, international donors – including 35 countries, major foundations and private donors pledged significant new resources. Between 2002 and 2004, contributions to the Global Fund totalled USD 2.3 billion, with an additional USD 1.1 billion pledged for the four-year period from 2005 to 2008. As of December 2006, pledges amounted to USD 6.6 billion through 2008.[85] Resource needs for 2007 was projected to USD 28.5 billion for the three diseases (malaria account for USD 2.9 billion).[86]

[84] www.theglobalfund.org
[85] The Global Fund web site: pledges and contributions, December 2006
[86] Investing in Impact, the Global Fund, 2006.

## B. Organisational Framework and Environment

### a. Global Fund Structure at Country Level:

At the country level, key Global Fund structure includes: the CCM; the PR; and, the LFA.

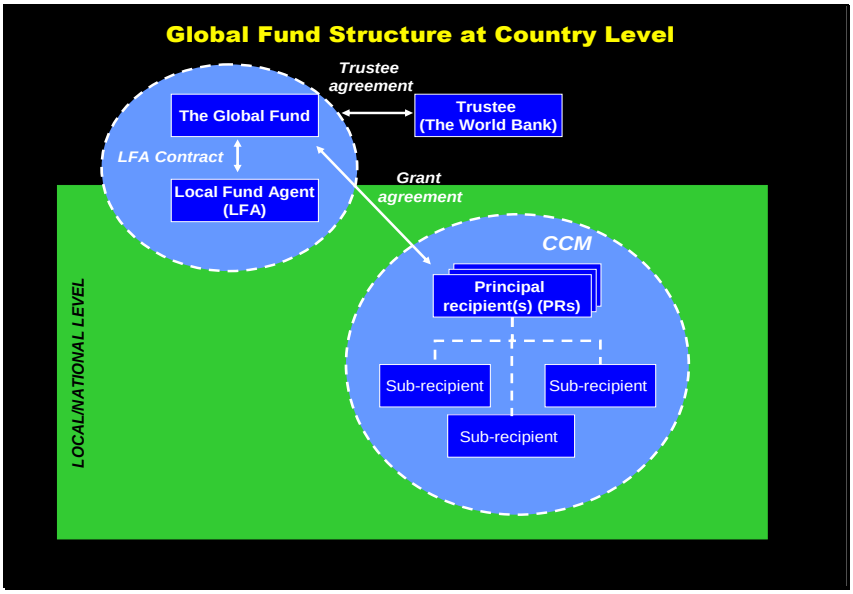


Fig. 4: Fiduciary arrangement: Board Presentation, October 2002.
Source: The Global Fund 2002.

### The Country Coordinating Mechanism

The CCM emulates representation of the Board at country level involving a multi-sectoral body with representatives from government, donor community, NGOs, private sector, community and faith-based organisations, and people living with the diseases. CCMs are required to review and endorse country proposals as well as play an oversight and governance role for post grant approval process and during implementation of Global Fund grant programmes. CCMs are responsible for:

i. providing timely responses to any request for clarification to their proposal from the TRP;
ii. nominating one or more PRs with the necessary capacities, according to the Global Fund's minimum requirements;
iii. monitoring implementation activities under the Global Fund approved grants;
iv. evaluating performance of these programmes; and,

v. ensuring linkages and consistency between the Global Fund and other health and development programmes in support of national priorities at country-level.

### The Principal Recipient

The PR is an entity nominated by the CCM and confirmed by the Global Fund to be legal entities responsible for the grant proceeds and implementation in a recipient country. There may be more than one PR in a given country. PRs are responsible for:

i. ensuring that they have the required capacities for successful proposal implementation, according to the Global Fund's minimum requirements;
ii. completion of the necessary implementation plans including a monitoring and evaluation plan with appropriate targets and indicators in accordance with the Global Fund's performance-based funding system and the goals and objectives specified in the proposal; and,
iii. efficient and timely interactions with the LFA during the PR assessment and with the Secretariat during grant agreement negotiations.

### The Local Fund Agent

The LFA is an independent entity selected and contracted by the Global Fund to assess the capacity of the PR to administer funds prior to grant agreement and grant signing. During the implementation stage, the LFA's role is to oversee and verify reported data and related information regarding the financial and programmatic progress of the grant. LFAs are responsible for:

i. efficiently conducting the PR assessment and assisting during grant negotiations according to the guidelines provided by the Global Fund;
ii. efficient, timely and constructive interactions with the PR and the CCM during the PR assessment and grant negotiation process;
iii. review PR periodic request for funds, undertake site visits to verify results and review PR's annual audit report;
iv. review grants for Phase 2 renewal process; and,
v. assist the Global Fund grant closures.

The reporting procedure including data verification and disbursement requests are highlighted in Figure 5.

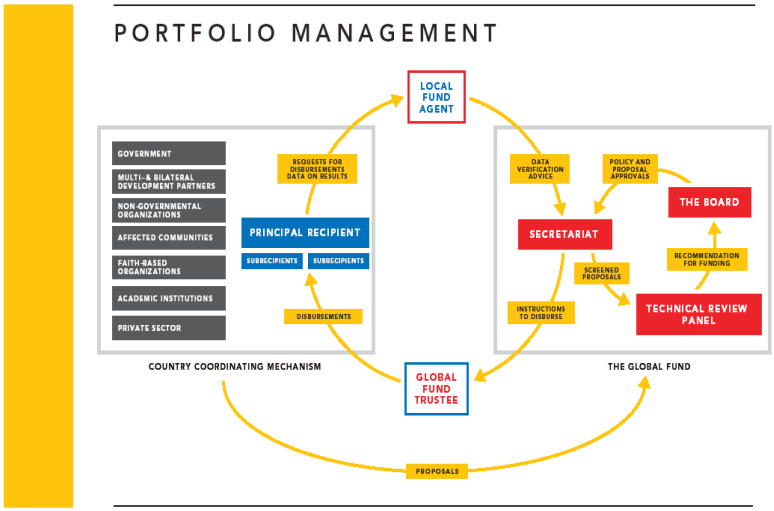


Figure 5: Global Fund Portfolio Management, Source: Global Fund June 2005

## B. Global Fund structure at the Headquarter Level:

At the global level, key Global Fund structure includes the governing Board, the Secretariat, the Technical Review Panel and the Partnership Forum as described below:

### i. The Board

In accordance with its mandate, the Global Fund is governed by an equal number of stakeholders with representation from donors and recipient countries holding seven seats in each sector, Civil Society includes two seats for North and South NGOs, and two seats for the private sector (one foundation and one business). The technical partners (i.e. WHO, UNAIDS, and the World Bank), and a representative from communities living with the diseases sit on the Board as non-voting members. The Board provides an oversight role and also sets policy for the Global Fund. There are several working groups including portfolio management and procurement committee, monitoring and evaluation and finance committee, and resource mobilisation committee, which meet in between Board meetings to discuss respective policies and procedures.

### ii. The Secretariat

A Secretariat based in Geneva and is responsible for the day-to-day management of the Global Fund programme and activities including Board relations, support to the TRP, liaison with the Trustee (the World Bank), CCMs, PRs and the LFA. The Secretariat operates on less than 3% of the contributed funds annually for central administration and management of the Global Fund.[87] The Secretariat is responsible for:

i. acting as an efficient intermediary between a CCM and the TRP;
ii. contracting of a experienced LFA;
iii. providing CCMs and PRs with appropriate information about the Global Fund's policies and procedures;
iv. efficient and timely interactions with CCMs and PRs during the PR assessment and grant agreement negotiations; and,
v. oversee grant implementation including grant renewals and grant closures.

### iii. The Technical Review Panel

The Chair and Vice-Chair are selected by the TRP from its membership and approved by the Board. The Chair is to serve for one year after approval by the Board at the end of which the Vice-chair serves as the Chair. Each year, the TRP will propose a new Vice-chair to be approved by the Board.

The TRP comprised of 22 experts from around the world is an independent, impartial panel, entrusted with the task to review proposals based on technical merits. The TRP was expanded from 17 members to 22 members for Round 2 review – one additional member for each of the three diseases and two more for the crosscutting group. The TRP is composed of 4 members each for Malaria and Tuberculosis, 7 members each for HIV/AIDS and in cross-cutting groups with expertise in public health, clinical management, socio-behavioural sciences, and developing country experience. The cross-cutting group members have expertise in policy and health systems development, as well as an understanding for finance, economics, and public policy. The TRP is responsible for providing timely and substantive feedback to the responses received from the CCMs.

[87] The Global Fund to Fight AIDS, Tuberculosis and Malaria, April 2003.

### iv. The Trustee

The World Bank as the Trustee for the Global Fund, undertakes fiduciary responsibilities for collection, investment and upon request, disbursement of the funds to the Principal Recipient. The World Bank has also provided assistance in the areas of fiduciary and operational issues.

### v. The Partnership Forum

The Global Fund's by-laws also call for the formation of a broad group of stakeholders referred to as the Partnership Forum, which is expected to convene biannually to review progress and provide counsel to the Global Fund.[88] Beginning in December 2004, a Partnership Forum meeting was held together with the International HIV/AIDS Conference in Bangkok, Thailand, followed by a second Partnership Forum meeting in Durban, South Africa in July 2006.

### vi. The Partners

In addition to the World Bank there are other development partners including UNAIDS - providing technical support, strategic analysis, policy advice, monitoring and evaluation; WHO, plays a key role in operational, technical and capacity building efforts related to Global Fund programmes at regional and country levels. WHO also serves as the host for other global communicable disease initiatives such as Roll Back Malaria Secretariat and the STOP TB Partnership.

[88] The Global Fund to Fight AIDS, Tuberculosis and Malaria, April 2003.

## C. The Proposal Process

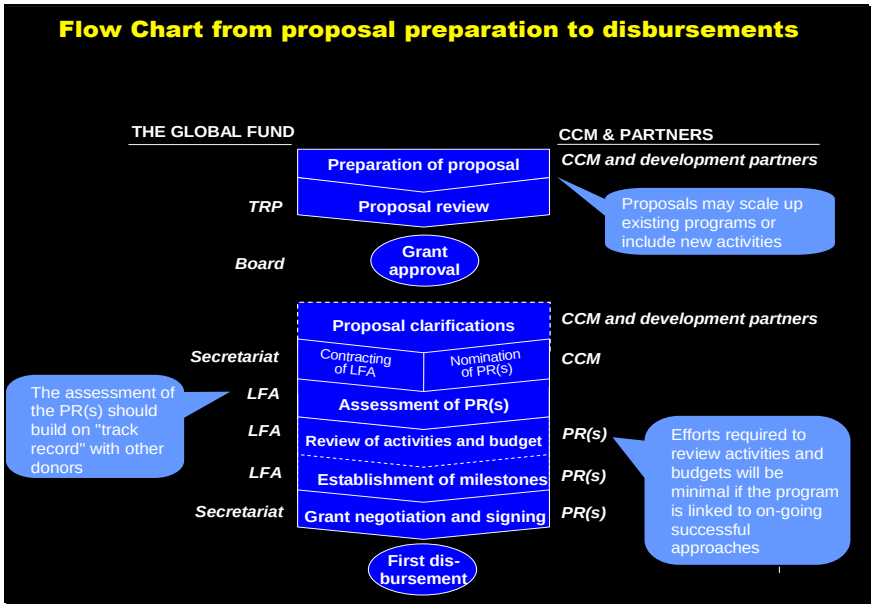


Fig. 6: Global Fund Proposal Process. Source: Global Fund October 2002

Countries are encouraged to submit coordinated proposals through a multi-sectoral CCM body for AIDS, Tuberculosis and Malaria. Eligible proposals are reviewed by the TRP and recommended for Board approval based on availability of funds. Based on LFA assessments, a two-year grant agreement is signed for approved proposals. The various steps and procedures are illustrated in Fig. 6. Further funding for the remaining years is contingent upon programme performance and availability of additional funds.

## D. Proposal Submission to Approval:

### a. Call for Proposals

**Round 1:** Shortly after the establishment of the Global Fund, a call for first round of proposals was issued online. Countries were given one month for proposal submission. One hundred and ninety proposals were received. The Global Fund Board approved 65 programmes in 36 countries for a total of USD 565 million.[89]

[89] http://www.theglobalfund.org/en/apply/current/

**Round 2:** The call for Round 2 proposals was announced in July 2002 with a deadline for proposals at the end of September 2002. The Global Fund received 115 proposals from around the world comprised of 230 components. Ninety-eight components from 65 countries, (45 of which are new countries) with a request for USD 5.2 billion over a 5-year period was recommended for funding by the Fourth Board of the Global Fund, which met in Geneva on 29-31 January 2003. The Global Fund approved a total of 98 programmes for 73 countries for a total of USD 866 million.

**Round 3:** The call for Round 3 proposal was announced in March 2002 with a deadline for submission in May 2003. Unlike the previous year, there was only one call for proposals for that year and for subsequent rounds. The Global Fund approved 71 programmes in 61 countries for a total of USD 623 million.

**Round 4:** The call for proposals for Round 4 was announced in January 2004 with a proposal submission date of April 2004. The Board approved 72 programmes in 52 countries for a total of USD 1,039 billion.

**Round 5:** The call for proposals for Round 5 was announced in March 2005 with a proposal submission timeline of June 2005. The Board approved 67 programmes in 60 countries for a total of USD 770 million.

**Round 6:** The call for proposals for Round 6 was announced in May 2006 with proposal submission timeline of August 2006. The Global Fund Board approved 87 programmes in 63 countries for a total of USD 846 million.

### b. Screening Process (scope, eligibility criteria)

When the proposals are received by the Secretariat, the proposals are registered and screened based on a set of criteria. The screening process focused on three main areas: validity of scope; source eligibility; and, completeness of proposal.

**Validity of Scope:** ensures that all applications are associated with the three main diseases (HIV/AIDS, Tuberculosis and Malaria). Proposals, which are related to research[90] and pre-investment, are screened out.

[90] with the exception of operational research (e.g. data on resistance prevalence, distribution of vulnerable populations, and transmission vectors via operational research linked to service delivery).

**Source Eligibility:** looks for inclusiveness of proposals (e.g. information on CCM members and completeness of signatures, minutes of CCM meetings etc.). There is strict adherence to guidelines for non-CCM applications by requiring CCM endorsements. Proposals, which are submitted without CCM endorsement, must prove to fall under the following three exceptions outlined in the framework document: 1) countries without legitimate governments; 2) countries in conflict or facing natural disasters; and, 3) countries that suppress or have not established partnerships with civil society and NGOs.

**Completeness of Proposals:** The Proposal Screening Team conducts a quality check to ensure that the proposals, which are submitted to the TRP, are complete. The team screens for CCM eligibility criteria (e.g. budget consistency, completeness of attachments, required signatures from the CCM etc.). Once complete, the proposals are then marked eligible for the TRP review process.

### c. The Review Process

The TRP meets for a period of two weeks after each round of call for proposals when the proposals have been submitted and screened by the Secretariat. The Chair of the TRP assigns experts to meets in small groups of 2 or 3 (including at least one cross-cutting technical expert) to review the proposals. The TRP receive the proposals at least 4 weeks prior to the meeting. The reviewers are assigned primary and secondary roles during the review process. The criteria for review are based on: soundness of approach (i.e. technical soundness and is in accordance with international best practice); feasibility (related to implementation and management); potential for sustainability (e.g. high political commitment, additionality); and evaluation and analysis (e.g. focused results, measurable set of indicators, and monitoring and evaluation mechanism).

At the end of each day, the TRP reconvenes at plenary session to present their findings and recommendations. On the last day of review, TRP makes a final decision on each of the category groups during the full day plenary session. Category 1 is marked as "recommended with little or no clarifications/modifications". Category 2 is marked as "recommended with some clarification/modification". Category 2B is similar to Category 2 marked as "recommended with some clarification/modification" with the exception that under a resource constrained environment, Category 2 approved proposals receive priority over Category 2B approved proposals. Category 3 is "not recommended for funding but strongly encouraged for resubmission" and Category 4 is "not recommended

for funding."[91] This categorisation is similar to GAVI's review process with four levels of acceptance: 1) immediate acceptance; 2) accept with clarifications (within one month); 3) conditional acceptance (within 5 months); and, 4) resubmission.[92]

In order to address conflict of interest and confidentiality, TRP members are asked not to represent positions of the Global Fund partners nor review proposals that represent a perceived conflict of interest. If TRP members are engaged in work in a particular country, members excuse themselves during plenary sessions when the proposal categories are being deliberated. Technical partners (e.g. WHO and UNAIDS) also participate in the TRP in providing support to the proposal review process for verification of data.

### d. The Board Approval Process

At each Board Meeting after the call for proposals, the recommended proposals submitted by the TRP are taken up as a block based on assigned categories for a decision on funding.

**Implementation Arrangements:** Once the Board approves the proposals, the Secretariat initiates and facilitates the TRP clarification processes between, CCM contact persons (and/or PR if identified) and the primary and secondary reviewers of the TRP. The Chair of the TRP then provides the final approval and countries receive official notification from the Global Fund. There are four stages from Board approval to disbursement of funds. These include:

**1) PR nomination by the CCM:** CCM selects a legally accountable representative to receive funds and manage the programme. The intended innovative approach is that the PR can either be from the public or private sector and there can be more than one PR in the country. For example, for Round 1 grants, Sri Lanka nominated one PR for its public sector disbursements and one PR from the NGO sector for private sector disbursements. Similarly, in Haiti, UNDP served as the PR for public sector activities and a private banking institution oversaw disbursements to approximately 20 NGOs.

[91] See Section V for additional information on performance rating system.
[92] Murphy, C., 2002 p. 33

**2) LFA selection and appointment by the Secretariat:** The mandate to be a lean Secretariat has forced the Global Fund to outsource its services as part of the private-public initiative. In organisational management terms, outsourcing is defined as the strategy of purchasing services or components from suppliers to prevent overextending the firm beyond its core capabilities.[93] The LFA plays a facilitating role between the PR and the Global Fund Secretariat and is seen as the eyes and ears of the Global Fund in country. A key criterion is the independence from the implementing PR and a substantial in-country presence. The intended innovative approach has been based on the contributions from the various expertise from the public and private sectors.

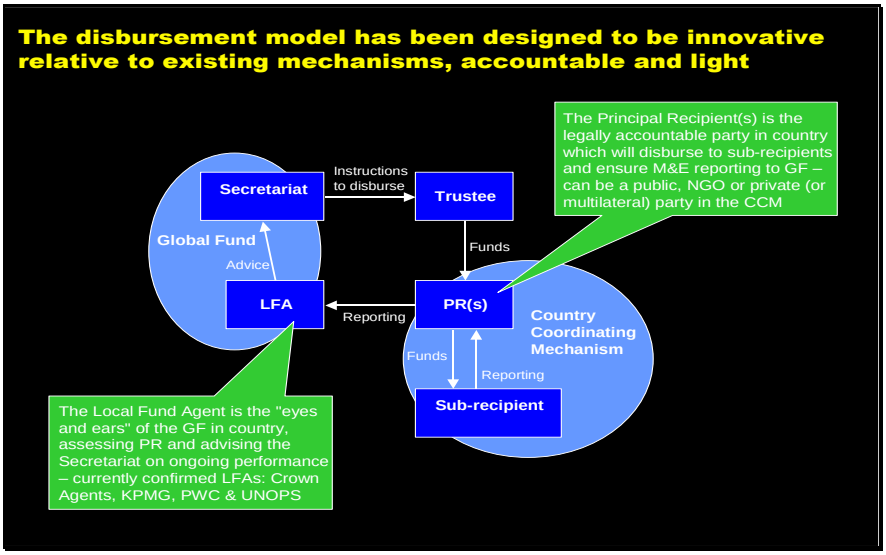


Fig. 7: Global Fund Disbursement Process, November 2002.
Source: The Global Fund 2002.

**3) Confirmation of PR:** The LFA conducts assessments of the PR against minimum capacities, including fiscal, programme management, procurement and monitoring and evaluation oversight. The intended innovative approach is that the assessments are light while maintaining accountability and transparency.

**4) Grant Negotiations and Agreement:** The grant agreement includes a work plan of the PR which provides clear indicators of progress and agreed milestone to measure PR and programme performance. The intended innovative approach is that the indicators

[93] Cook and Hunsaker, 2001 p. 56

include measures of fiscal responsibility, programme progress and outcomes, as well as CCM functionality, partnership and additionality.

### E. Processes and Key Achievements:

This Section highlights how the Global Fund is exercising the learning technique, i.e. “learning by continuous improvement” in the Global Fund operational processes.

#### i. Improving Proposal Guidelines (Round 1 and Round 2)

The call for Round 1 proposals was made one month after creation of the Global Fund. Proposal submission was at the end of March, 2002, giving countries approximately one month to prepare a proposal, create a CCM and with their endorsement, submit the proposal to the Global Fund. Proposal guidelines were also less clear. As a result, the majority of the proposals received by the Secretariat varied in quality and some of the approved proposals did not contain a detailed budget breakdown or activity plan.

Country feedback from Round 2 processes showed significant improvement over Round 1. There was an overall improvement in quality in terms of presentation and completeness. This is attributable to several key factors:

1) the revised guidelines and forms were seen as more transparent and clearer to applicants;
2) timeframe for Round 2 (i.e. three months versus one month for Round 1);
3) technical support provided by key partners (e.g. WHO, UNAIDS) further strengthened country proposals during proposal preparation phase. For example, in Asia both WHO/WPRO and WHO/SEARO had regional meetings for countries, SEARO conducted a peer review or "mock TRP review" process; and,
4) organisational improvement enabled the Secretariat to acknowledge all proposals within one week of deadline for submission. The majority of all the proposals were screened within ten days of the deadline and where necessary, further information was requested from applicants.

## ii. Improving Proposal Guidelines (Round 2 and Round 3)

**Proposal Form:** information was provided to help assess additionality. Countries classified in Low Middle Income and Upper Middle Income were requested to describe their plans on co-financing. A table was added to reflect total budget required for each of the diseases, sources and amount available and needed. A question was included on the functionality of Sector Wide Approaches (SWAp) or other pooling mechanism. The Green Light Committee (GLC) application was attached for multi-drug resistant TB as well as a work plan template and an annex on the coverage indicators was included.

**Principles and Partnership:** In Round 3 proposal guidelines, a preamble was included to explain the principles of the Global Fund. The word "Partnerships in countries" instead of "Countries" was used to emphasise the importance of the involvement of all stakeholders.

**Elaboration on Eligibility Criteria:** An important consideration was the provision of eligibility criteria based on the World Bank classification of countries income. Annexes of list of countries that were illegible were added.

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**Country Coordinating Mechanism:** emphasis was placed on CCMs to build linkages to broader national coordination efforts at country level including Poverty Reduction Strategies and Sector Wide Approaches.

**Proposals Evaluation:** The conditions for evaluation are same as the previous Rounds although additional emphasis was given to the issue of sustainability. Balance of interventions, where applicants are encouraged to apply both for scaling up existing programmes or new approaches.[94]

**Taxes and Tariffs**: This information was added in the guidelines to alert applicants that the Global Fund strongly encourages the relevant authorities in recipient countries to

[94] These could include the provision of drugs and commodities for treatment and care.

obtain exemptions from duties and taxes for all products financed by the Global Fund grants and procured by NGOs or any other PR or sub- recipients.[95]

**Principal Recipient:** Further clarification was provided for the roles and responsibilities of the PR including the requirements for the PR's minimum capacities.

**Upper and Lower Limits:** In previous rounds, there was no ceiling placed for each proposal submitted by countries. Based on the Board decision, no specific ceiling amounts were mandated on the size of the application. However, evidence of sufficient absorptive capacity was outlined as an important criterion for programme support.

**Implementation Plans:** Proposals should be supported by a detailed Action Plan for the first year (versus 6 months for Round 1 proposal) with an indicative plan for the second year of the grant period. This was done with the expectation that the PR would be revising its year two work plan at the end of year one.

**Local Fund Agent:** The concept of LFA was introduced clarifying the role of LFA as an independent entity selected by the Global Fund.

**Monitoring and Evaluation:** The section was simplified with the use of the term "indicators" only. The levels of monitoring had been clearly explained (e.g. results-based reporting) with examples.

**Procurement and Supply Management:** Much more details were provided than previous Rounds where guidelines reflect the Global Fund policy in procurement, which sought to ensure that quality products were obtained at lowest prices through competitive purchasing from qualified manufacturers and suppliers. It highlighted the different elements of the procurement plan.

### iii. Improving Implementation Arrangements (4 start-ups to 40)

The Global Fund began its grant negotiations and implementation efforts in four countries for Round 1 approved proposals - two countries in Africa (Tanzania and Ghana), one country in Latin America/Caribbean region (Haiti), and one country in Asia (Sri Lanka). Four Fund Portfolio Managers were sent to countries in August-September, 2002 to kick-

[95] In Round 1 grant agreements, tax exemption letter was made a condition precedent to disbursement.

start the process. Upon return, lessons learned were taken into account and an assessment was made to determine the feasibility of rolling out the remaining 36 countries before the upcoming Board meeting planned for end January 2003. The approach reflected team learning, personal mastery and mental process models. Based on lessons learned, the Global Fund recognised that FPMs were spending considerable amount of time in countries (on average ranging from three to eight weeks), to assist with the development of work plans of the PRs. This process was compounded by the fact that policies and guidelines were still in the development stages. The assessment also determined that the current start up pattern could not be sustained for the remaining 36 countries, especially in light of the limited number of portfolio managers at that time. A decision was then made to streamline the operational guidelines. This decision-making process showed learning by experimentation and continuous improvement.

**The Process:** A two-step approach was introduced to sign grant agreements to allow countries additional time for the development of appropriate implementation arrangements and plans required for Round 1 proposals. The implementation phase was divided into two parts: 1) Step 1 Assessment, which required the countries to develop a six-month work plan and for the LFA to complete the first of four assessments,[96] mainly the financial management and systems assessment. Step 2 was initiated when the PR had completed work plans and budgets for the full two-year programme, but no later than six months after grant signing. These two elements were made a precondition to the grant agreement.

As part of the Grant negotiations, the Global Fund and each PR agreed on the key milestones and estimated associated expenditures for at least the first six months. The LFA, the entity responsible for reviewing the detailed work plans and budgets of PR would then make appropriate recommendations to the Secretariat.

Once the milestones for monitoring of results during the first two quarters have been agreed and the Secretariat has received assurances that each nominated PR has the required minimum capacities and systems for financial management and disbursement, grant negotiations can then take place. The Grant Agreement includes the agreed

[96] These assessments focus on four main functional areas: i) institutional and programmatic capacity, ii) financial arrangements (only to the extent that issues remain from the assessment in the first step), iii) procurement and supply chain management, and iv) monitoring and evaluation capacity.

milestones for the first two years of the programme and, as necessary, conditions precedent to disbursement and other required needs for the PR.

Upon signing of the Grant Agreement, an initial disbursement of funds is made to each Principal Recipient. The first disbursement for each grant was limited to one-third of the first year's budget, or a total of USD 1.5 million. The PR may then submit a disbursement request (with financial and programmatic progress reports indicating the achievement of key milestones and accountable use of resources) for additional funds as required.

Based on the work plans and budgets, the PR and the LFA review appropriate quarterly milestones for the two-year period. The LFA will then make appropriate recommendations to the Global Fund Secretariat.

For the earlier grant agreements, streamlining this process allowed more time for the PRs to develop a full two-year work plan within the first six months and the LFAs to continue with the three remaining assessments: a) the institutional and capacity management assessment; b) procurement assessment;[97] and, c) the monitoring and evaluation assessment. The six-month time frame also allowed additional time for improvement of the results-based disbursement approach, an essential part of the monitoring and evaluation component. By introducing this flexibility, the Global Fund Secretariat was able to sign 31 grant agreements within a two-month period.

### iv. Introduction of an Interim LFA Arrangements for Round 2

Interim LFA arrangements were put in place to proceed with Round 2 assessments to allow for an expansion of the LFA contractor base. The Global Fund Secretariat launched an open competition to expand the base of the four existing LFAs (i.e. PricewaterhouseCoopers, KPMG, UNOPS and Crown Agents). Additional LFA entities were contracted which included Swiss Tropical Institute and Emerging Market Group.

**Round 1 Activities:** The Global Fund Secretariat decided to carry out the reminder of Round 1 LFA work until the open LFA competition process is complete (i.e. remaining Step 2 Assessments and short-term implementation oversight functions) by retaining the existing LFA in a given country. If the existing LFA for a country has completed Step 1

[97] A condition precedent to the grant agreement is the completion of procurement assessment by LFAs prior to the start of any procurement activities by the Principal Recipient.

Assessment, the same LFA would be retained for the Step 2 Assessments and the first 3-6 months of the implementation contract, provided that the Secretariat was satisfied with the work, which had been completed to date. Round 1 implementation work orders were limited to 3-6 months with the exception of those contracts that had already been issued for the full two-year period.

**Round 2 Activities:** While the open competitive processes were being put in place, the Global Fund engaged with existing LFAs for the Round 2 Assessments and covering short-term implementation work orders for Round 2 to cover the period until the completion of the worldwide competitive LFA process.

There were approximately 15 Round 2 countries, which overlapped with Round 1 countries (i.e. those countries that were approved grants for both rounds) and there were approximately 45 "new" countries from the Round 2 with successful proposals. For the 15 overlapping countries, the Global Fund continued to engage the existing Round 1 LFA in a given country. For assessment work in the "new" countries, the Global Fund solicited expression of interest from the 4 existing LFAs by requesting costing proposals and to award framework contracts for a country, groups of countries or on sub-regional basis.

This approach allowed for the introduction of the global competitive bidding process while at the same time continue the LFA assessments to advance towards grant negotiations and grant signing for Round 2 approved proposals.

### v. Introduction of an Internal Appeals Mechanism

A new policy introduced based on the outcome of the Fourth Board Meeting, was the Internal Appeal Mechanism in order to provide country applicants with an option to have their applications reconsidered, as the only recourse mechanism. Eligibility criteria was based on any proposals which had not been recommended in its current form (Category 3) and/or rejected (Category 4) by the Global Fund Board twice in consecutive Rounds of Proposals.

Other policies have been established such as the Phase 2 grant renewal process and more recently, the Rolling Continuation Channel (otherwise known as Beyond Phase 2). The new funding policies are described in more detail in Section V.

There were also new tools and policies developed since November 2005 which include: Disbursement Request/Progress Update; LFA Data Verification; New Grant Agreement; Repeat PR Assessment Tool; New Monitoring and Evaluation Toolkit; and requirement for a two-year "attachment" for all new grants.

## F. Challenges and Constraints

### a. Implementation Challenges

For Round 1 grant agreement and implementation efforts, the task of grant signing was performed under extraneous circumstances. Although there were more processes in place for Round 2, the signing of Round 2 grant agreements had been affected by pressure to disburse Round 1 grant agreements, and dealing with implementation issues, placing more work load on the already overburdened portfolio team.

While the experimentation and continuous improvement model has proven to be flexible in adapting procedures and the necessary documentation format, this approach had not been conducive to those portfolio managers relying on previous versions of forms to implement changes in mid-course with new and revised formats. This created frustration amongst FPMs and at times leading to confusion at country level.

LFA interim arrangements for Round 2 had to be made with the expansion of LFA entities at the same time to solicit an expression of interest and costing proposals from the existing LFAs compounded to the already heavy work burden of the Secretariat. Pressure to sign grant agreements based on LFA assessments and to continue to increase the disbursement profile prior to the G8 Summit was another concern. Shortage of interim and permanent staff to manage the increasing workload continued to be a challenge.

### b. Reasons for delayed grant signings

**Global Fund start-up processes:** For grants approved in Rounds 1 and 2, there were delays for grant signings which were associated with the Global Fund's start-up processes. There were significant delays particularly for Round 1 grants, as grant signing policies and procedures had to be developed, Secretariat staff had to be recruited, and LFAs had to be contracted through competitive tender. For Round 3 grants and onwards,

such start-up delays were addressed. However, there were factors beyond the control of the Secretariat that influenced the speed of grant signings, as further described below.

**TRP clarifications:** For several grants approved in Rounds 1 and 2, there were substantial delays due to the time before CCMs responded to the TRP's requests for clarifications. In view of these delays, the Global Fund Board stipulated the current maximum time limit for the CCM to submit its initial response (6 weeks) and for the TRP clarification process to be finalized (4 additional months) in October 2003.

**PR arrangements:** For Round 1 grants, CCMs had not been requested to submit a PR nomination as part of their proposal. This was addressed in the revised proposal guidelines and form for Round 2 and onwards. However, despite the instructions in the proposal form, some CCMs did not submit their PR nomination with their Rounds 2 and 3 proposals. For such proposals, there were delays as the Secretariat had to wait for the CCMs to submit their PR nominations. In other cases, the PRs nominated by certain CCMs did not meet the Global Fund's minimum capacity requirements. In most of these instances, measures were identified to strengthen the capacities of the nominated PRs through negotiations between that PR and the Secretariat which required some time to complete. In a few cases, the Secretariat had to request CCMs to submit an alternative PR nomination, with further delays.

**Preparation of implementation plans:** A PR may require substantial time to prepare its implementation plans as necessary before the PR and the Secretariat can complete grant agreement negotiations. The time required by PRs to prepare their implementation plans have been the most common reason cited for delays in grant signings.

# SECTION V. PERFORMANCE-BASED FUNDING OF THE GLOBAL FUND

## A. Background

The Global Fund is mandated to be a financial instrument (rather than an implementing agency) by significantly increasing resources to scale up activities. In seeking to establish a simplified, rapid disbursement mechanism, the Global Fund adopted a performance-based funding approach to achieve rapid disbursement of funds linked to programme results. Performance-based funding as one of the driving principles of the Global Fund is a critical component, as results achieved from the first two years of grant funding are contingent upon future programme funding of the approved country proposals.[98] The grant renewal process is part of the performance-based funding approach and is intended to provide incentives for grantees to focus on results and timely implementation, identify challenges and opportunities to improve programme performance with CCM oversight. Performance-based funding measures would allow for resources to be freed up from non-performing grant programmes for reallocation to other programmes where results can be achieved.

## B. The Global Fund Evaluation and Measurement Framework

As the Global Fund's additional disbursements of funds to the PR are based on demonstrated results and financial accountability, the PRs are requested to submit periodic or quarterly disbursement requests with financial and programmatic progress reports indicating achievement of key milestones and outputs. These disbursement requests are sent to the Secretariat through the Global Fund's local representative, the LFA after review and recommendation. The intended innovation was a light reporting requirement (e.g. no line item disbursement requests are required as the financial information was only aggregated at the objective level) linked to programmatic progress. The overall M&E framework and measures which were put in place to ensure progress and accountability were reflected within four levels: Impact; Systems Effect; Grant Performance; and, Operational Performance as outlined in Figure 8 below.

[98] The Global Fund Board approves proposals up to five years but only makes a financial commitment for the first two years.

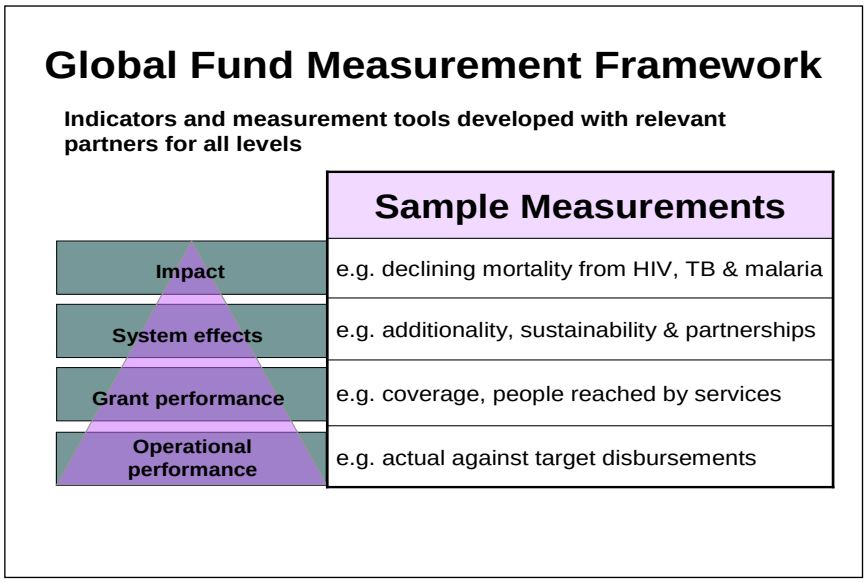



Figure 8: The Global Fund's Four Levels of Measurement. Source: The Global Fund 2005

**Impact Level:** is defined as the ultimate measure of the success of the Global Fund. Impact indicators are included in all grant agreements, and the Global Fund's contribution at the global-level (e.g. MDGs).

**System Effects:** assesses the impact indicators (both positive and negative) that the Global Fund has on the existing systems through which it works in particular in funded countries.

Grant Performance relating to Phase 2 renewal process and Operational Performance which relating to grant implementation activities will be described in more detail, later in this section.

**Operational Performance**: includes measures for the performance of the core functions of the Global Fund and its Secretariat, including resource mobilisation, grant management, proposal and grant signing, disbursements and Secretariat costs. The Global Fund's performance measurements include but not limited to: reaching planned targets; disbursements and utilisation of funds; procurement activities; sub-recipient performance; timely reporting; verification of data; and identification of opportunities/needs for technical assistance and programme support.

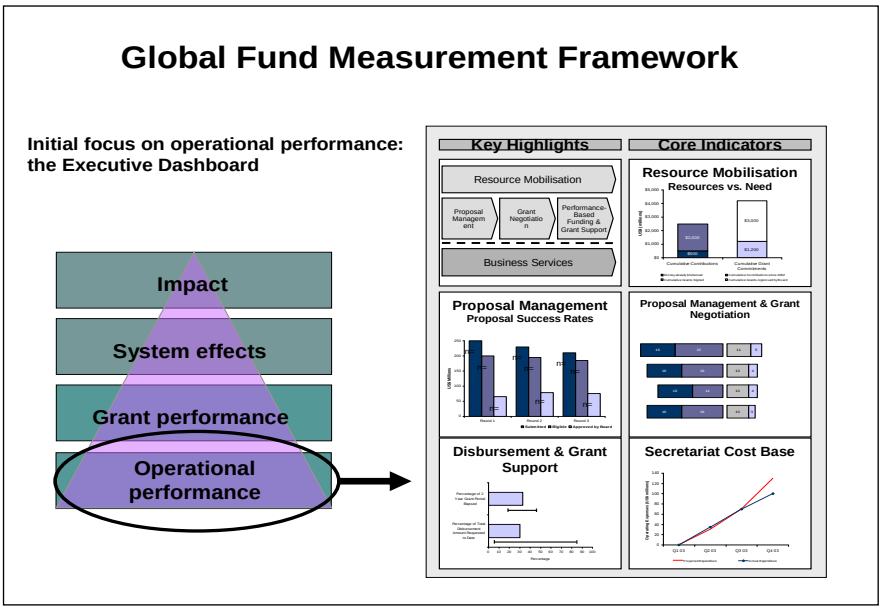



Figure 9: Global Fund Measurement Framework. Source: The Global Fund 2005

## C. Performance-based Funding Approach

**Fiduciary Management:** The PRs are requested to submit periodic or quarterly disbursement requests with financial and programmatic progress reports indicating achievement of key milestones[99] and accountable use of resources. PRs are responsible for managing, monitoring and revising annual budgets (as required) in order to respond to programme realities during implementation. The Disbursement Requests and Progress Reports prepared on a template by the Global Fund must contain: (i) a summary of financial activity during the quarter in question and cumulatively from the beginning of the Programme until the end of the reporting period; and (ii) a description of progress towards achieving the agreed-upon milestones set forth in Annex A to the Grant Agreement. The PR must provide information on variance between planned and actual achievements for the period in question. For all disbursements, the PRs are required to verify and maintain all necessary support documentation in accordance to the annual work plan, as specified in the Grant agreement.

[99] Achievement of milestones is a key point which will be discussed in later chapters.

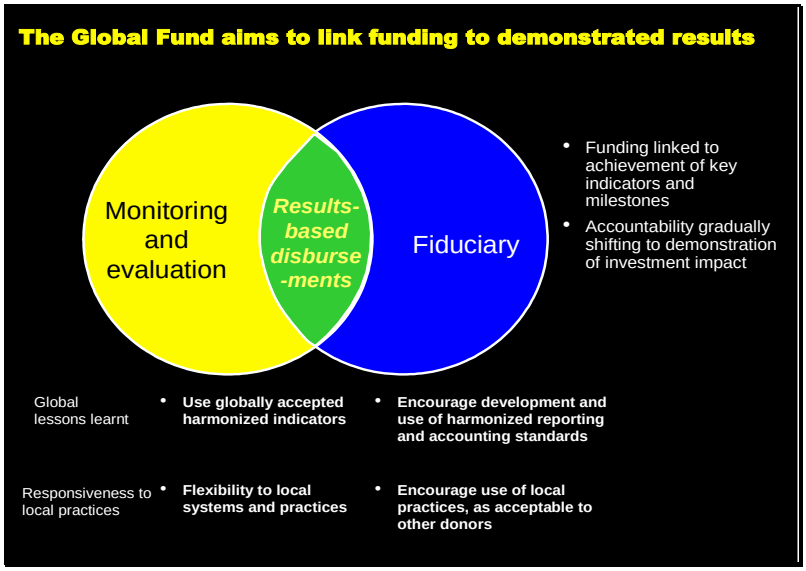



Figure 10: The Global Fund Results-based Disbursement. Source: Global Fund 2002

**Monitoring and Evaluation**: Monitoring is the routine tracking of the key elements of programme and project performance, usually inputs and outputs, through record keeping, regular reporting and surveillance systems as well as health facility observation through field units and client surveys. Evaluation is the periodic assessment of the change in targeted results that can be attributed to the programme or project intervention. Given the Global Fund's performance-based funding mechanism, the PRs must ensure that comprehensive monitoring and evaluation systems are in place to assess progress against intended verifiable results. The PR must submit an M&E plan which must include information on programmatic progress on a regular basis. The PRs are encouraged to submit to the Global Fund a limited number of indicators to monitor the performance of a grant, and the amount of co-financing. The indicators that will be reported to the Global Fund are outlined in Attachment 1 and 2 to Annex A of the Grant Agreement.[100]

[100] Annex A of the Grant Agreement contains programme description and information on programme implementation (e.g. proposal name, title, grant number, disease component and agreed upon PR). Annex A also contains conditions precedents which are tied to disbursement tranches, drawn from PR capacity assessments, LFA recommendations, grant negotiation process between the FPM and the PR. Attachment 1 and 2 list agreed upon target indicators for the specific proposal.

## D. Background on Reprogramming

As part of the results-based disbursement approach, the PRs are provided with the flexibility to reprogramme the grant during the implementation period. In general terms, reprogramming is defined as a change in the "rules" of the grant, (i.e. workplan or activity plan, budget, indicators). A change in the "rules" governing the grant is seen as a change in the legal relationship. Therefore, reprogramming changes are changes reflecting the legal relationship between the PR and the Global Fund Secretariat (i.e. any change stemming from the original content of the Grant Agreement). These may be approved in advance by setting "reprogramming rules" for small changes (e.g. 10% allocation of funds between budget line items), but may require formal approval or a change in the Grant Agreement for changes that are significant in nature.

For any change in the Grant Agreement, the CCM should be informed and notified for information or, where significant, for "approval" of all significant changes in the Grant. Though the CCM has no legal "right" to approve the change, the PR may coordinate the change prior to the request, and the Secretariat may require CCM consent before approval.

Significant reprogramming (or material reprogramming), is defined as a change which is so substantial that it is questionable whether the TRP would have approved the proposal as revised (i.e. a change which impacts the "proposal development" process). For example, substantial changes in targets, dropping or adding an activity (depending on the scale), introducing a new treatment intervention (normally not dependent on the scale).

In cases of significant reprogramming, the Secretariat is required to send the proposed changes to the TRP for approval, a switch from the "grant monitoring" process in order to reaffirm the results of the "proposal development" process. Due to special circumstances of malaria reprogramming efforts initiated by the Global Fund's change in drug policy, specific tools were developed for malaria grants transitioning to ACT as described in Sections VI and VII.

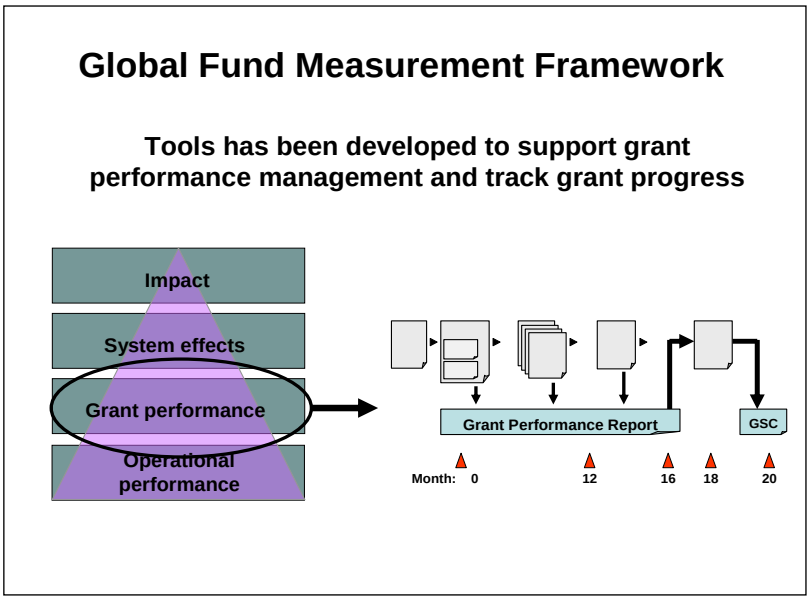



Figure 11: The Global Fund Grant Performance Process. Source: The Global Fund 2005

Grant Performance includes measures for the performance of grants and is the foundation of ongoing performance-based funding decisions of the Global Fund. In collaboration with technical partners, the Global Fund developed a joint Monitoring and Evaluation Toolkit, which defines simplified measures across the three diseases and is available to guide grant recipients in determining their programme indicators as attachment to the Grant Agreement.

### E. Phase 2 Grant Renewal Process

At a 2004 Global Fund Board meeting, policies and procedures for Phase 2 grant renewals were approved based on recommendations prepared by the Global Fund Board sub-committees. The Seventh Board agreed on a policy for continuation of grant funding beyond the initial two-year commitment. The Grant Performance diagram above describes the elements required for Phase 2 grant renewal process.

In addition, the Technical Evaluation Reference Group (TERG) reviews the soundness of the Phase 2 review and decision process and report to the Board. The TERG was also tasked with a formal review of the Phase 2 grant renewal policies and procedures based on lessons learned for presentation to the Board.

**Review and Decision Process**

The Board delegated the Phase 2 grant renewal review and decisions to the Secretariat according to the policies and criteria set forth by the Board. As part of the Phase 2 renewal process, the Secretariat was tasked to: i) review relevant information for the Phase 2 grant renewal; ii) at its discretion, request the TRP to perform a second review of CCM Requests that involved significant reprogramming from the original approved proposal; iii) commit grant funds for Phase 2; iv) negotiate grant agreement extensions with PRs including performance targets for Phase 2; and v) regularly report to Board sub-committees on the results of Phase 2 grant renewal reviews and decisions.

The Board in turn agreed to: i) establish and periodically review the policies and procedures for Phase 2 grant renewals; ii) through its Chair and Vice Chair, decide to discontinue grants based on reviews by the Secretariat and the TRP; and, iii) at each Board meeting, receive reports from the portfolio sub-committee on Phase 2 grant renewal decisions.

**Exceptions for Phase 2 grant renewals for Rounds 1 and 2 grants**

It was recognised by the Board that during the Global Fund's first two years of operation, grant recipients might have been adversely affected by lack of clarity regarding Global Fund policies and procedures. The Board further recognised that grant performance information might not have been as systematically collected as intended. For Round 1 and Round 2 grants, the Board agreed that start dates within grant agreements could be adjusted to reflect programme realities. For certain Rounds 1 and 2 grants, operational adjustment of the performance rating system was made for situations where targets were ill-defined.

**Special Considerations for Ongoing Drug Treatment**

At the Eighth Global Fund Board Meeting in 2004, the Board specified four areas to be undertaken by the Secretariat which included: Phase 2 renewals in resource constrained environment; special considerations for grant programmes involving ongoing drug treatment; data quality assurance; and technical assistance to enhance implementation capacities.

The Board recognised that funding for programmes involving ongoing treatment was necessary if the Global Fund is committed to policies that will sustain long-term treatment. Strategies for phasing out funding from the Global Fund for such programmes that involve treatment therefore needed to be explicitly considered up-front and jointly by partners, since isolated decisions on discontinuation of funding might have negative consequences for affected population.

Ongoing treatment considerations were also affected by the Global Fund's Comprehensive Funding Policy which stipulated that funding beyond the first two years of grant implementation receives priority over the funding of new proposals. The Board also recognised ongoing treatment considerations might be subject to discontinued funding for a programme as a result of the Global Fund's performance review for Phase 2 grant renewals, or during implementation according to the Global Fund's performance-based funding including risks associated with insufficient funding for Phase 2 grant renewals in resource constrained environment, and, discontinued funding at the end of the five-year proposal period.

In addition, the Secretariat was asked to seek contextual information and input from in-country partners on risk of discontinuation of funding for submission to the Board prior to the Board's decision for No Go grants for Phase 2.[101] The contextual information would include the actual amount necessary to sustain treatment until the end of the proposal period (remaining years 3-5 for Phase 2) to cover for patients that receive ongoing treatment within programmes for which overall funding would be discontinued (in the case of a no-go renewal decision or in the event of insufficient resources and a "first due; first access" system) or in the event of insufficient resources.

The amount to be granted for continuation of ongoing treatment would be calculated based on current treatment costs per patient in the country in question to be reviewed and revised on a yearly basis. The ongoing treatment grant would be accessible from a special account by the partner administering the ongoing treatment programme for the remaining period of the original Board approved proposal period.

[101] Performance Rating System and Phase 2 decision process will be explained in more detail later in this Section.

## F. Policy Background on Phase 2

Phase 2 grant renewal decisions are made according to clear criteria for satisfactory grant performance and contextual considerations, subject to resource availability. Continuation of grant funds is conditional upon satisfactory programme performance and the availability of resources. The decisions are based on systematically collected information made available by the Global Fund through Grant Fact Sheets and Grant Score Cards, and updated periodically on the Global Fund website.

### Resource Considerations

Resources for Phase 2 are based on the Global Fund's Comprehensive Funding Policy, where funding for renewed commitments to existing grants have priority over new grants particularly in situations of limited available resources. At the beginning of each calendar year, the Global Fund Secretariat estimates the total amount of resources necessary for renewed Phase 2 grant commitments for that year. The remaining amount pledged to the Global Fund for that calendar year may be made available for new rounds of grant. Resource projections, new contributions and related financial updates are regularly reported to the Board at Global Fund Board meetings.

## G. Grant Performance: Phase 2 Grant Renewal Process

### The Phase 2 grant amount and programme objectives

The Phase 2 grant renewal decision is based on grant performance during the initial period (Phase 1 or years 1-2 of the proposal) along with contextual considerations, the Phase 2 budget, objectives and intended results in the CCM's Request for Continued Funding. The Request for Continued Funding is completed by the CCM, and must include:

- The CCM's assessment of performance to date;
- Complementary contextual information;
- Proposed Budget for Phase 2;
- Programme objectives (which should be broadly in line with the original, approved proposal); and,

- Intended results for Phase 2, i.e., Attachment 3 to Annex A (third year results) broken down by reporting period, and intended results for years 4 and 5.

Grant performance during Phase 1 is used as a guide to the decision for Phase 2 grant amount. The maximum grant amount for Phase 2 is based on the original approved Proposal less the amount spent during the initial grant period.[102] CCMs are given the latitude to "reprogramme" as necessary and appropriate to reflect programme realities. Uncommitted funds revert back to the Global Fund's general resource pool as a result of the Phase 2 grant renewal process. The amount requested by the CCM may be adjusted for reasonableness by the Secretariat, assisted by advice from the LFA, based on:

i. The usage of funds and performance during phase 1;

ii. Foreseen programme realities for phase 2 (including grantees abilities to accelerate implementation as compared to Phase 1); and,

iii. Budget reasonableness of key unit costs (e.g., any commodities which may have fluctuated in price since the original approved proposal).

In cases of significant reprogramming, the Secretariat reviews the CCM's Request and at its discretion request a second review by the TRP, specifically if the CCM Request involves a change in programme objectives, e.g., in terms of disease interventions, or a substantial reduction in targets.

## Grant Performance Report

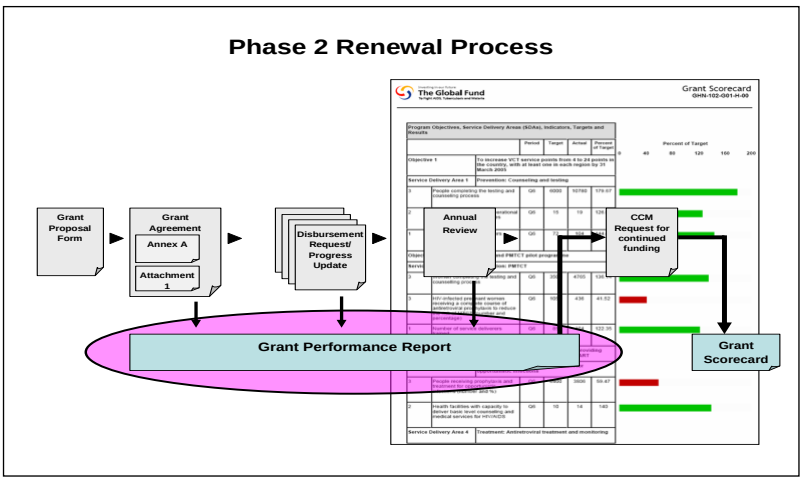



Figure 12: The Global Fund Phase 2 Renewal Process. Source: The Global Fund 2005.

[102] The amount in the original Proposal, following TRP clarifications and phase 1 grant negotiations, less the amount disbursed by the Global Fund to PRs at the end of the phase 1 period.

The Grant Performance Report (GPR) is essentially a Fact Sheet, comprised of objective information on the grant's performance. The GPR is provided to the PR for review in order to ensure that the data used to analyze the grant is correct. The GPR would include:

- A list of each of the indicators included in the Attachment 1 and 2 of the Grant Agreement;
- General Information on the Grant from the Grant Agreement;
- Reported results against intended results;
- Actual disbursements made against planned disbursements;
- Major audit findings (if any); and
- Major recommendations from the LFA (if any).

The information is compiled through the Global Fund's grant information systems and the CCM's Request for Continued Funding. The key information for Phase 2 grant renewal decisions is reflected in the Grant Score Cards which are made available including through the Global Fund website.

**Phase Two Decision Panel**

The Phase 2 Decision Panel at the Global Fund includes members of the Executive Leadership Team of the Global Fund, and technical specialists. The Panel reviews the recommendation of the cluster (i.e. the Fund Portfolio Manager and the Team Leader), and then gives the cluster an opportunity to provide additional information as required. The Panel will often question the cluster before taking a decision on Phase 2. The decision is then communicated to the PR and CCM by the Fund Portfolio Manager.

The majority of the decisions have been marked GO (performance rating A) and CONDITIONAL GO (performance rating B).[103] A GO decision includes time-bound actions, or conditions, but these are generally done through negotiation rather than through contractual obligations. Increasingly, the Phase 2 Decision Panel has been cutting budgets in order to channel additional resources to successful countries. Thus, the PRs and CCMs need to provide sound justification for their unspent budget at the time of submission.

[103] See figures 14 and 15.

## Decision Criteria

The Phase 2 grant renewal decisions fall into one of four categories and grant renewal decisions are based on criteria for grant performance and contextual considerations as outlined below:

**Performance Rating System**

| Decision category | | Grant Performance rating | | Contextual considerations |
|---|---|---|---|---|
| "Go"<br>Phase 2 grant committed for the remaining proposal period (years 3-5) |  | A<br>expected or exceeding expectations | and | No or minor contextual issues |
| "Conditional go"<br>Phase 2 grant committed conditional upon time-bound actions to be taken by the PR/CCM (maximum 1 year) |  | B1<br>Adequate | and/or | Major contextual issues that can be addressed by the PR/CCM |
| "Revised go"<br>CCM/PR reprogramming (targets and Budget substantially revised for Phase 2) subject to Global Fund approval |  | B2<br>inadequate but potential demonstrated | and/or | Major recent improvements in program supporting environment |
| "No go"*<br>Phase 2 grant not committed<br>*requires Board Decision |  | C<br>unacceptable | or | Critical contextual risks beyond PR and/or CCM control |

Figure 13: Performance Rating System. Source: The Global Fund 2004

A grant performance rating system reflects actual programme results as compared to targets in grant agreements. Funding is not continued unless grantees demonstrate credible potential to reach programme targets.

**A**: Expected or exceeding expectations (generally when greater than 80% of the intended results indicated in Attachment 1 and 2 are achieved)

**B1**: Adequate (generally between 50 and 79% of the intended results are achieved)

**B2**: Inadequate but potential demonstrated (generally between 30 and 49 % of the intended results achieved)

**C**: Unacceptable (below 30% of the intended results achieved)

The grant performance ratings are made in view of country disease trends and impact. In addition, contextual information such as major changes in the programme supporting environment, significant adverse external influences (force majeure), financial and

programme management issues,[104] and systematic weaknesses, are also taken into consideration.

**Timing**

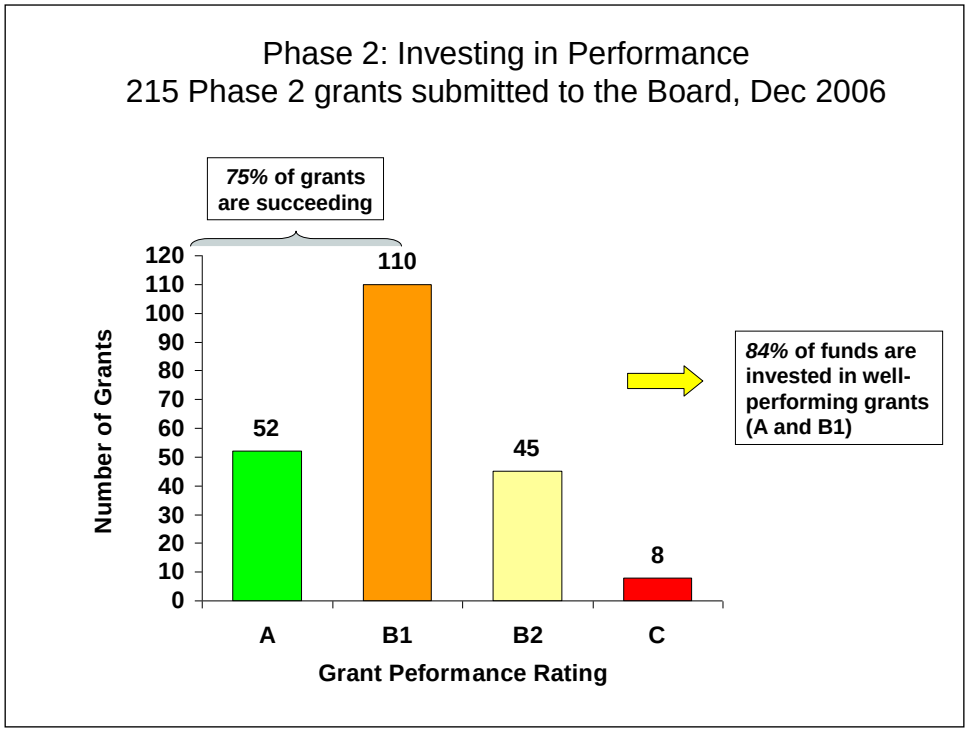
Phase 2 grant renewal decisions are normally considered 20 months after the programme start date with exceptions for *force majeure* situations.[105] A decision to discontinue funding is normally taken by month 22. Extensions to the normal timeframe for Phase 2 decisions are only granted in *force majeure* situations.[106]

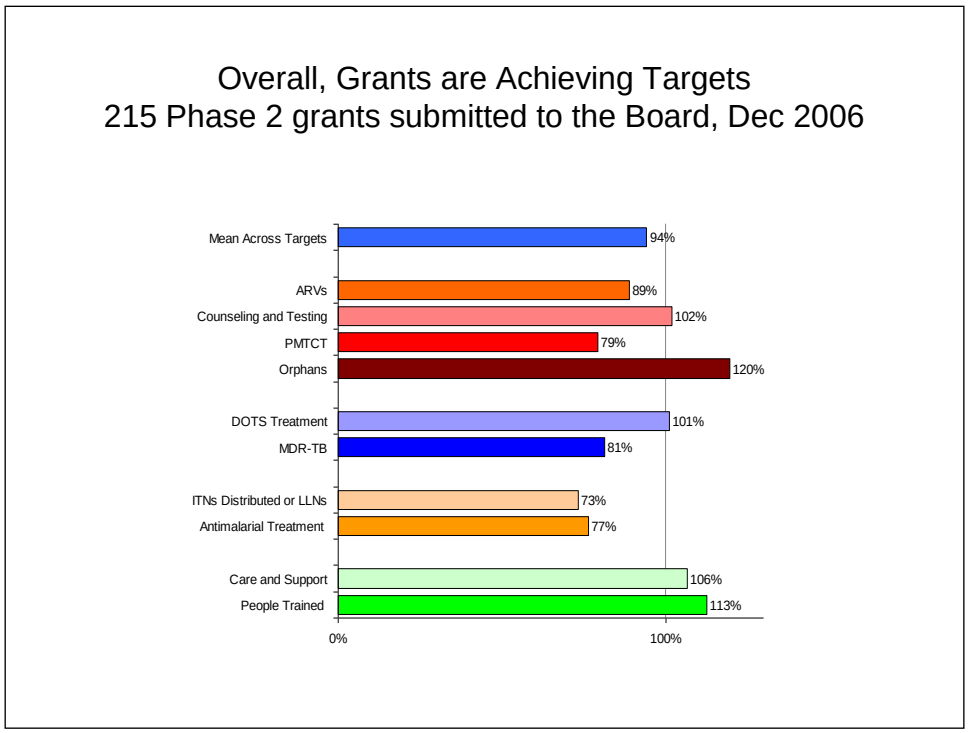
A CCM could Request for Continued Funding for Phase 2 decisions ahead of schedule in cases of accelerated implementation,[107] and/or severe exchange rate fluctuations. The decision timeline is adjusted for these cases accordingly. It was also recognised that Grant Agreements for an approved proposal were concluded at different points in time depending on the readiness of PRs and other country circumstances.

## H. Performance of Global Fund Grants to date

As of December 2006, the Global Fund had signed grant agreements totalling USD 5.3 billion for 410 grants in 132 countries. More than 60% of grant funds were disbursed to PRs. A total of 215 grants from 117 countries had undergone Phase 2 review process based on progress achieved during Phase 1 implementation activities. Seventy five percent met or exceeded targets receiving a GO or Conditional GO (i.e. A or B1 rating), 21% received a Revised Go (a B2 rating) and 4% received a No Go (i.e. C rating).[108] See Figures 14 and 15 below.

[104] E.g., slow or incomplete disbursements to sub-recipients or issues with a PR
[105] The program start date is defined as when a PR receives its first disbursement from the Global Fund. The date of the fist disbursement from the Trustee to a PR plus one week.
[106] E.g., the SARS epidemic in China, major natural disasters, civil unrest or war. Although in practice with later grants, the Global Fund has had to provide extensions to Phase 2 grant renewal based on delays associated with internal processes.
[107] Accelerated implementation was envisaged for malaria reprogramming efforts.
[108] The Global Fund, Partners in Impact, 2007, p. 45.




Figures: 14 and 15: Grant Performance Rating and Achievement of Targets.

Source: Global Fund 2006

In 2006, results for the Global Fund top three indicators (see Annex 4 Global Fund Top 10 indicators) showed results exceeding targets – ARVs (120%), DOTS (167%), and ITNs (128%) of planned targets.[109]

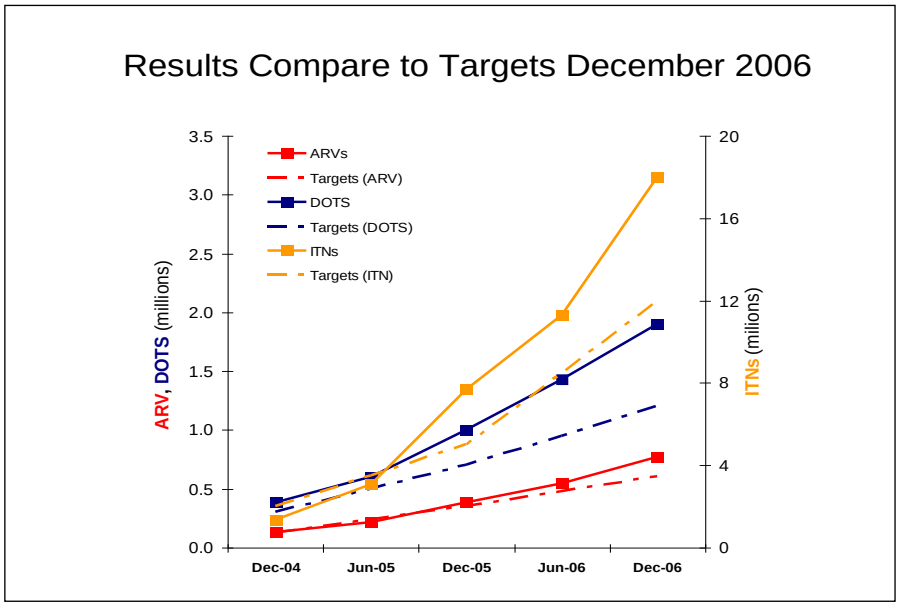



Figure 16: Results against Targets for Global Fund grants. Source: Global Fund 2006

## I. Performance of Malaria Grants

Malaria accounted for one third (29%) of Global Fund allocation from Rounds 1-5, ranging from 12% in Round 1 to 40% in Round 4. The Round 4 allocation of approximately USD 413 million more than doubled the average allocations in Rounds 1-3 mainly due to the increase in the request for ACTs. Budget allocations for Coartem and other ACTs increased from USD 3.9 million in Round 2 to USD 89.9 million in Round 4. The cost of drugs accounted for 54% of all recommended funding for malaria.

The TERG[110] noted that overall, proposals submitted for malaria funds were the least successful, with 34% recommended on average ranging from 17% in Round 1 to 54% in Round 4. Similarly, Partners for Impact Report identified weak areas on the Phase 2 review in malaria grants citing achievements of 73% in the insecticide treated net (ITN) distribution and coverage and 77% for treatment whilst acknowledging slow progress

[109] The Global Fund. Partners in Impact, 2007. p. 16.
[110] is advisory body providing independent technical advice to the Global Fund Board

due to procurement and global supply shortages related to long lasting insecticide treated nets (LLITNs) and ACTs.[111]

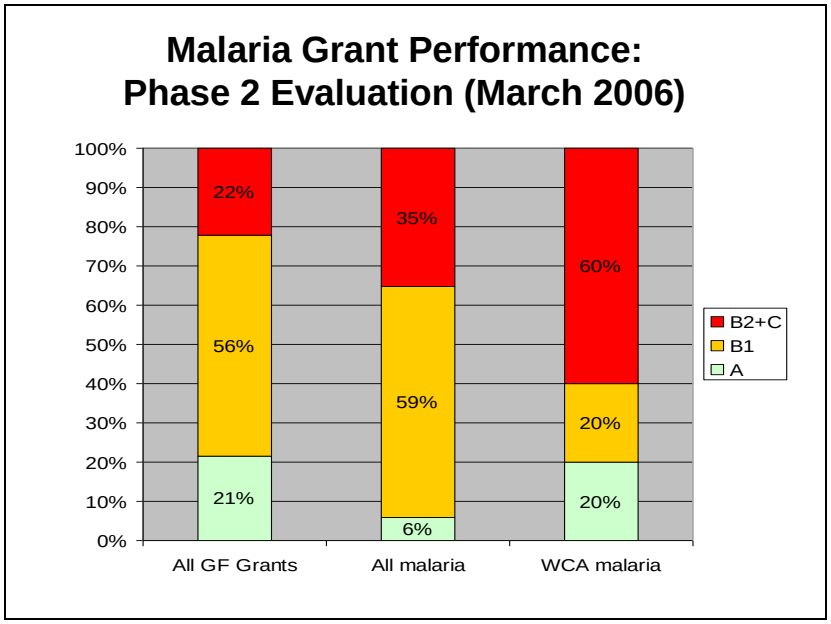



Figure 17: Presentation from West and Central Africa Malaria Workshop.
Source: Global Fund March 2006[112]

## J. The Global Fund Data Quality Framework

The Global Fund Data Quality Framework was introduced later and relies on three levels: i) LFA on-site "spot-checks" at service delivery points; ii) M&E strengthening tools made available for countries; and, iii) independent data quality audits including but not limited to assessment of health information systems in countries and verification of data quality reported for key indicators at selected sites.[113]

The Global Fund developed data quality audits and tools in collaboration with PEPFAR, WHO, USAID and MEASURE Evaluation Group for joint implementation and monitoring of Global Fund grants. The purpose of the DQA Protocol was designed to: a) verify that appropriate data management systems were in place; b) verify the quality of reported data for key indicators at selected sites; and c) contribute to the overall M&E systems strengthening and capacity development efforts.

[111] The Global Fund. Partners for Impact, p. 47, 2007.
[112] Figure 17 shows that of March 2006, malaria grants compared to all Global Fund grants were the least successful, 6% for A ratings, 59% for B1 and 35% for B2 and C ratings.
[113] The Global Fund. Partners in Impact, 2007. p. 28.

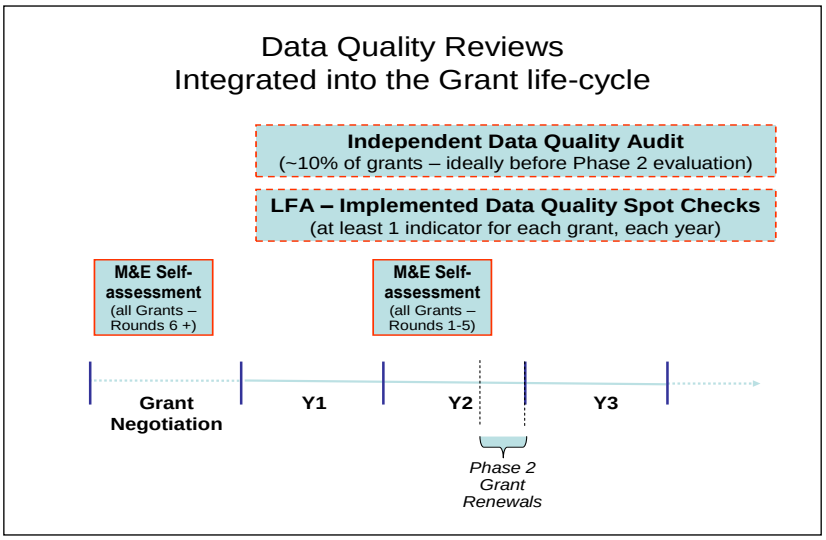



Figure 18: Data Quality Reviews 2006-2007. Source: Global Fund 2006

DQAs have been introduced on a pilot approach in a number of countries and by end 2007, it was envisaged that approximately 10% of the grants would be follow-up for DQAs.[114]

## K. Rolling Continuation Channel (Beyond Phase 2)

In 2006, the Global Fund established an additional funding window known as the Rolling Continuation Channel (RCC), which provided an opportunity for CCMs to apply for continued funding for grants that are reaching the end of their funding terms under conditions different from those available for proposals submitted as part of new rounds of financing.

Under this funding stream, the Global Fund reviews of all grants before the end of their Phase 2 to determine whether the countries would qualify to apply for continuation of funding through the RCC. The key factors in determining grant eligibility were based on: 1) whether the grant received performance ratings from the Global Fund of "A" in more than half of its reviews of the grant's progress updates over the 18 months preceding the determination of qualification; 2) whether the grant demonstrated potential for impact (which was defined as contribution to a national effort that has had or had the potential in the near future); and, 3) measure of impact on the burden of the disease.

[114] The Global Fund. Investing in Impact, 2006, p. 36.

The Global Fund also took into consideration whether the grant was sustainable, by the extent to which the grant can demonstrate linkages to a national plan inclusive of civil society and the private sector and transparently showed the financial contributions to the plan by major funding sources, including domestic sources, and whether in exceptional cases unexpected changes in circumstances have had a material negative impact on programme implementation.

The CCM is notified if the Global Fund Secretariat determines that a grant is eligible to apply for funding through the RCC. A proposal submission was still required for continued funding for evaluation by the TRP. The proposals may cover a maximum of six years (in two phases of three years each), with funding in the second phase subject to the approval of the Board based on a mid-term evaluation. It was estimated that only one quarter to one third of Global Fund grants that expire in a given year would be eligible to apply for the RCC.

The next section provides background on ACT and specific tools created within the performance-based funding to facilitate ACT reprogramming efforts.

# SECTION VI. BACKGROUND ON MALARIA AND ARTEMISININ-BASED COMBINATION THERAPY

## A. The Global Burden

Globally, estimates of new cases for malaria range from 300-500 million each year which results in over one million deaths annually.[115] The global malaria burden has shown increasing levels of malaria morbidity and mortality, reflecting the deterioration of the malaria situation in Africa during the 1990s. About 80% of all malaria deaths occur in Africa, and the great majority of them in children under five.[116]

## B. What is Malaria?

Malaria is a parasitic disease transmitted by mosquitoes, caused by a one-cell parasite called plasmodium.[117] The parasite is transmitted from person to person through the bite of a female Anopheles mosquito, which requires blood to nurture her eggs. There are four types of human malaria; *Plasmodium (P.) vivax, P. malariae, P. ovale* and *P. falciparum. P. falciparum* malaria is most common in Africa, and the most fatal form of malaria accounting for high mortality in many regions.[118]

The malaria parasite enters the human host when an infected Anopheles mosquito takes a blood meal. Inside the human host, the parasite undergoes a series of changes as part of its complex life-cycle. Its various stages allow plasmodia to evade the immune system, infecting the liver and red blood cells, and finally develop into a form that is able to infect a mosquito again when it bites an infected person. Inside the mosquito, the parasite matures until it reaches the sexual stage where it can again infect a human host when the mosquito takes her next blood meal, 10 to 14 or more days later.[119]

[115] Novartis Media Release. December 22, 2004. p. 2
[116] RBM InfoSheet. http://www.rbm.who.int/cmc_upload/0/000/015/372/RBMInfosheet_1.htm
[117] It was once thought that the disease came from fetid marshes, hence the name mal aria, (bad air) until the discovery of plasmodium in 1880.
[118] RBM InfoSheet. http://www.rbm.who.int/cmc_upload/0/000/015/372/RBMInfosheet_1.htm
[119] Ibid.

## C. Treatment Background

The main factor contributing to the increasing malaria mortality and morbidity is the widespread resistance of *P. falciparum* to standard antimalarial drugs (e.g. chloroquine, sulfadoxine–pyrimethamine and amodiaquine). Multidrug-resistant *P. falciparum* malaria is widely prevalent in South-east Asia and South America and increasingly in Africa. Resistance to inexpensive monotherapies such as chloroquine and sulfadoxine–pyrimethamine (SP) is on the rise. Other contributing factors include the inappropriate use of antimalarial drugs during the past decade where antimalarial drugs as monotherapies were deployed on a large scale, and were poorly monitored in their continued usage despite high levels of resistance.[120]

Over the past decade, artemisinin compounds, especially artesunate, artemether and dihydroartemisinin – have been used against multi-drug resistant *P. falciparum.* To date, no resistance to artemisinin or artemisinin derivatives has been reported. If used alone, the artemisinins will cure *falciparum malaria* in 7 days, but studies have shown that in combination with certain synthetic drugs they produce high cure rates in 3 days with higher adherence to treatment. Furthermore, there is some evidence that use of such combinations in areas with low to moderate transmission can slow down the development of resistance to the partner drug.[121]

As a response to increasing levels of resistance to antimalarial medicines, WHO recommends that all countries experiencing resistance to conventional monotherapies, such as chloroquine, amodiaquine or sulfadoxine–pyrimethamine, should use combination therapies, preferably those containing artemisinin derivatives (e.g. artemisinin-based combination therapies) for *P. falciparum* malaria. In addition, WHO lowered the recommended resistance-threshold for treatment policy change from 25% to 10% as assessed by standard WHO protocols in children under five years of age for adoption of a more effective treatment.[122]

WHO recommends the following combination therapies:[123]

[120] RBM Infosheet: Facts on ACTs, January 2006 Update. http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm
[121] Ibid.
[122] Ibid.
[123] Note: Amodiaquine plus sulfadoxine/pyrimethamine may be considered as an interim option where ACTs cannot be made available, provided that efficacy of both is high.

1. artemether/lumefantrine;
2. artesunate plus amodiaquine (in areas where the cure rate of amodiaquine monotherapy is greater than 80%);
3. artesunate plus mefloquine (insufficient safety data to recommend its use in Africa); and,
4. artesunate plus sulfadoxine/pyrimethamine (in areas where the cure rate of sulfadoxine/pyrimethamine is greater than 80%).

### D. What is Artemisinin-based Combination Therapy?

Artemisinin-based Combination Therapy uses a combination of antimalarial drugs, the key component of which is an artemisinin derivative (e.g. artesunate, artemether or dihydroartemisinin).[124] These four derivatives have approximately five times higher potency than artemisinin but with a shorter shelf life. ACTs are highly effective against malaria parasites by acting as schizonticidal and gametocidal in the liver stages (i.e. rapidly kills most of the Plasmodium parasites).[125] ACTs are recommended as the most optimal treatment regime for non-complicated malaria.

Artemisinin is extracted from A. annua, which has been used for medicinal purposes in China since 340 AD. It was recommended as a treatment for chills and fever which was recognised as symptoms of malaria. The active ingredient “Quinghao-su” or artemisinin was first isolated by Chinese scientists in 1972 as part of an antimalarial drug discovery programme in response to North Vietnam’s request during the Vietnam War.[126]

A. annua is endemic to Asia, occurring naturally in northern parts of China at 1,000-1,500 meters above sea level. China began domesticating A. annua after its discovery in 1972, followed by Vietnam and Thailand in the 1980s. It is cultivated as an annual crop in China and Vietnam for artemisinin and in Romania and Bulgaria for its essential oils. Production has also started in East and West Africa (notably Ghana, Gambia, Kenya, and Tanzania) and some in India. The crop is being grown in the United States and Australia on an experimental scale.[127]

[124] KIT Royal Tropical Institute, 2006. p. 12
[125] WHO: Global Malaria Programme. 2006. p. 12
[126] FAO: Artemisia annua; the plant, production, processing and medicinal applications. Downloaded from http://ecoport.orog/ep?searchtype-earticleView&earticledId=727&page5695
[127] KIT Royal Tropical Institute, 2006. p. 25

Artemisinin is found mainly in the leaves and flowers of A. annua. The leaves are harvested when the artemisinin content is highest and dried leaves are used (with 13% or less water content) for artemisinin extraction.[128] Artemisinin annua is an annual plant, with a crop cycle of approximately six months. It is seeded in February in the northern hemisphere and grows in the nursery for 80 days before being transferred to the field, where it grows for a further 100 days. The plant is harvested just before it flowers, and the leaves are air-dried for storage and extraction.[129] Cultivation for A. annua requires a minimum of six months and an additional two to five months are needed for production timelines depending on product formulation.[130] On average, the production cycle can take 16-18 months from planting to availability of finished product.[131] Business aspects of production are also complex and additional time is required in the A. annua production cycle (see table below).

**Table 2. Business Aspects of Production of Artemisia Annua:**

| Business component | Matters for consideration |
|---|---|
| Input supply | Seedlings – Production inputs |
| Extension and training | Grower's manual – GAP guidelines – Producer groups |
| Research and monitoring | Agronomic trials – Monitoring and evaluation |
| Credit provision | Company or bank – individual or group lending |
| Leaf collection | Collection centre management – Payment procedure |
| Price formula | First payment on delivery – second payment on checking – third payment after testing |
| Grower's contract | Right and obligations of grower – Rights and obligation of buyer |

Source : Global Malaria Programme, 2006

## E. Background on the shift to ACT Reprogramming of Global Fund Grants

Since 2002, the Global Fund has provided funding support for the procurement of malaria treatments to endemic countries. As of 2004, malaria endemic countries had been successful in obtaining a total of 63 grants for Rounds 1-3 totaling USD 483 million in support of various antimalarial interventions over 2 years. Of these, 44 grants include components for the purchase of antimalarial drugs, accounting for USD 60 million over 2 years and USD 118 million over a five-year period.

[128] FAO: Artemisia annua; the plant, production, processing and medicinal applications. Downloaded from http://ecoport.orog/ep?searchtype-earticleView&earticledId=727&page5695
[129] WHO: Global Malaria Programme. 2006. p. 21
[130] Novartis Media Release. December 22, 2004. p. 2
[17] KIT Royal Tropical Institute, 2006. p. 44

## F. Chronology of ACT Reprogramming

In 2004, 14 countries in Africa adopted ACTs from a total of the 37 countries. However, the most rapid change took place between 1 January and 30 August 2004 due to the following promoting factors: additional funding from the Global Fund; and international pressure to shift to ACTs based on drug resistance data. The following section describes the chronology of events leading to the process of reprogramming efforts and the shift to ACTs.

**Lancet Article (January 2004):** The pivotal international pressure came out of a Lancet article published in January 2004 citing the Global Fund for contributing to financing ineffective antimalarial drugs such as chloroquine and sulfadoxine-pyrimethamine, rather than the more effective ACTs and WHO for endorsing Global Fund proposals concluding that both "WHO and the Global Fund's current practices are not adequate to safeguard the best interest of malaria patients".[132] The article called for a rapid change to a more effective antimalarial drug (in particular to ACTs) and to accelerate efforts at country level.

**Global Fund Communiqué to Countries (January 2004):** On January 24 2004, five days after the publication of the Lancet article, the Global Fund Secretariat sent a letter addressed to CCM Chairs with attachments from the Lancet Article and the Global Fund's response to the letter. CCM Chairs were informed that the Global Fund proposals which were approved were viewed to be technically sound. Countries were encouraged to contact the Global Fund if recipient countries gather information that the approved treatments were not effective due to drug resistance so that the terms of the approved programme could be altered to allow for the use of a more effective treatment protocol including ACTs.

**Stakeholder Meeting (February 2004):** In February 2004, the Global Fund held a meeting with representatives of the authors of the Lancet article and the WHO/Roll Back Malaria Department to discuss the issues. It was agreed that all approved malaria grants from Rounds 1-3 applications be reviewed with respect to the available data on antimalarial drug efficacy for each country with the country's current treatment guidelines. The aim of this review was to compare all antimalarial drugs approved for

[132] The Lancet. Vol 363. January 17, 2004. p. 239

funding with the available data on therapeutic efficacy of these drugs, in order to identify grants needing a change of treatment policy.

**Malaria Grant review meeting (2 May 2004):** In May 2004, the findings were discussed with representatives of the authors of the Lancet article, the Scientific Community, WHO, RBM Partnership Secretariat; members of the Global Fund Technical Review Panel, the Global Fund Secretariat and other stakeholders at an informal malaria grant review meeting in Geneva to build consensus on the way forward. The meeting reviewed the available data on drug efficacy in all countries receiving funding for antimalarial drugs from the Global Fund, and agreed on recommendations on the way forward in assisting countries in reprogramming their grants based on available evidence at that time.

**TRP Review Process (3-14 May, 2007):** TRP members were provided with a briefing prior to the Round 4 proposal review process on the new data, reprogramming information by the Global Fund Secretariat and WHO.

**Information Dissemination (June 2004):** The Global Fund Secretariat then followed-up with countries to communicate the ACT reprogramming efforts and informing the TRP members. The final report was shared with interested stakeholders and the general public[133] in June 2004.

**Global Fund – RBM Joint Communiqué to Countries (28 June 2004):** A joint letter was sent to Ministers of Health stating Roll Back Malaria Partnership Board's endorsement in expressing its solidarity with country efforts to scale up access to ACT for the treatment of malaria as recommended by WHO.

**Bangkok Meeting (July 2004):** The RBM Partnership held a meeting in conjunction with the Global Fund Partnership Forum meeting held in Bangkok in July 2004 to advocate for increased malaria and ACT funding. It was estimated that countries would require up to USD 1 billion per year to purchase ACTs, which was considered to be 10 to 20 times the cost of traditional antimalarial drugs and that the Global Fund recipient countries would only be able to access up to USD 200 million for ACTs in 2004-2005.[134]

[133] subject to approval by owners of the original data sources and from the Principal Recipients.
[134] RBM Press Release, 9 July 2004.

**ACT Reprogramming Meeting in Nairobi (September 2004):** The Global Fund set up a consultative meeting with key technical partners in Nairobi, Kenya in September 2004 following the ACT review process. The meeting was a follow-up to the joint letter of the Global Fund and the Roll Back Malaria Executive Secretary to Ministers of Health that raised the issue of assuring timely access to ACTs. The meeting was to provide an opportunity for country teams to work with Global Fund Portfolio Managers and RBM partners to understand the technical aspects of adopting ACTs and the requirements of the Global Fund related to ACT reprogramming.

The meeting included a workshop where countries discussed their respective issues and challenges with the technical partners and the Global Fund Secretariat team to address quantification exercise and revising of procurement plans; an implementation timeline, and technical assistance requirements.

## G. Reprogramming of malaria grants from Round 1-3

The following section was extracted from an unpublished report as a result of a consultation meeting convened by the Global Fund on 2 May 2004 in Geneva.[135] The report describes the review process for reprogramming of malaria grants.

As a follow-up to the review process and the recommendations made at the grant review meeting, the Global Fund initiated a grant reprogramming process in countries, where drug efficacy data suggested a need for a change of first-line malaria treatment. The Global Fund stated that it would encourage and help facilitate this change in a dialogue with countries and other relevant stakeholders such as WHO. It was agreed that funding would be redirected for artemisinin-based combination therapies where appropriate. In countries, which were already in transition in changing their drug policy to ACT, the current status of this change would be assessed, so as to facilitate a rapid reprogramming of agreed funding from the Global Fund.

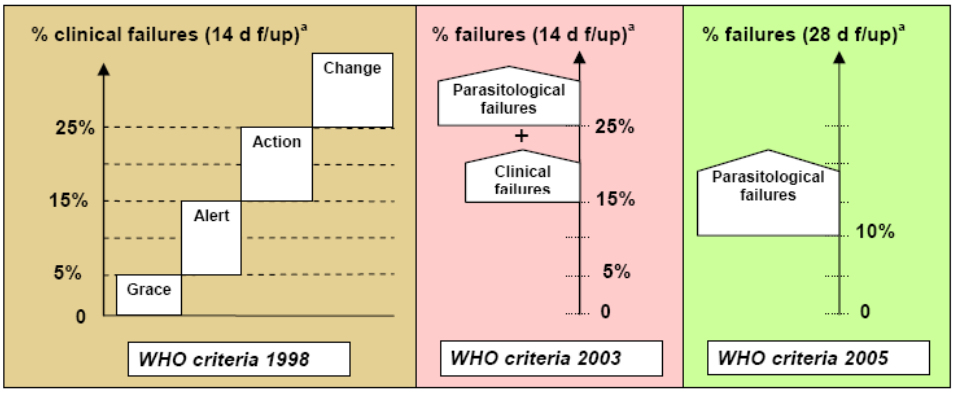
The meeting recommended that provision of updated information on antimalarial drug efficacy in countries should be a requirement for all future proposals to the Global Fund, and that this information be critically assessed as part of the proposal review process. It was agreed during the meeting that countries would be encouraged to set up systems to

[135] A Review of Antimalarial Treatment Choices for the Global Fund Approved Grants for Rounds 1-3. A Report of a Consultation Convened by The Global Fund to fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland, 2 May 2004.

monitor antimalarial drug efficacy on a routine basis, (i.e. to organise systems of country-wide sentinel sites where drug efficacy trials are conducted regularly), and the results are made available to Ministries of Health in a standardised format. Furthermore, all drug efficacy trials should use the most recent WHO standard protocol for drug efficacy testing, and should use 28 days of follow-up wherever possible. As the efficacy results obtained on day 14 tend to underestimate treatment failure rates, WHO stated that it would provide the most recent version of the standard protocol for drug efficacy testing.

WHO also agreed to endorse the choice of first-line antimalarial treatment by applicant countries in order to ensure that antimalarial treatments proposed for funding by applicant countries are consistent with the official WHO treatment guidelines. WHO's signature on future country proposals would signify endorsement of choices of drugs for first-line antimalarial treatment with the objective of viewing drug efficacy data as the main determinant of a drug policy change in a country.

WHO noted that most reported failure rates only reflect 14 days of follow-up, and that such estimates were often lower than the true level of resistance. Due to this underestimation, a more pro-active approach was advised. Moreover, WHO noted that it was generally advisable to consider drug policy change in a country before the WHO threshold is reached (i.e. clinical failure rates >15% and total failure rates >25%), in order to better control evolving drug resistance. With regard to the use of SP, there was a general consensus that SP should be used for intermittent preventive treatment in pregnancy, rather than deploying it as a general first-line antimalarial treatment. As SP is the only available treatment option for pregnant women, it was also noted that SP must be preserved for IPT to maintain a higher level of drug efficacy for as long as possible.




[a] d f/up = days follow-up.

Figure 19: WHO criteria for changing malaria treatment policy[136]

## H. Analysis of Data on Antimalarial Drug Efficacy

In order to conduct the analysis, available information on the 44 approved grants with antimalarial drug components for Rounds 1-3 were included in the review. Technical information on the grants, including the amount of approved funding and updated procurement information for specific drugs were made available by the Global Fund Secretariat. Details on the current national treatment guidelines for first and second-line drugs and for prevention of malaria in pregnancy were made available by the WHO/Roll Back Malaria Department, as well as all country-specific drug efficacy data from the database of the WHO. This database included all information on therapeutic efficacy of antimalarial drugs made available to the WHO/RBM Department. The sources of information include Ministries of Health, NGOs and research institutions, and published as well as unpublished data. Most of these efficacy data were established according to the WHO standard efficacy-testing protocol, but in some cases other protocols had been used. The analysis was mainly based on results of therapeutic efficacy tests; however, in some situations data from additional methods such as *in vitro* tests and molecular markers were also considered.

[136] World Health Organisation. WHO/HTM/MAL/2006.1113 http://www.who.int/malaria/docs/arusha-artemisinin-meeting.pdf

## I. Findings

There was a wide variation between countries with respect to the number of efficacy studies conducted regarding different drugs and drug combinations. There was also variation between the geographical coverage of sentinel sites for drug efficacy testing, and in the levels of transmission. In some countries, the coverage was high while in other countries, the number of studies was limited, and only represented few geographical sites. Sample size also varied widely; some studies reported on a large sample of study individuals, while other studies were more limited in terms of the number of patients available for analysis. Due to these differences, the report indicated that it was not easy to provide reliable efficacy estimates for different drugs. Conducting a form of meta-analysis of available studies, or assigning different weight to small and larger studies etc., would have also been difficult due to frequent changes and modifications made for efficacy testing protocols and due to variations in study design leading to missing information. As a consequence, the assessment of drug efficacy made for this review only considered simple summary estimates of reported failure rates for the different antimalarial drugs or drug combinations [median values, 25 and 75 percentiles and ranges], which should be interpreted with some caution. However, as the number of studies on chloroquine and sulfadoxine-pyrimethamine used, as monotherapy were generally high, the estimates for these drugs were relatively precise. The assessment included a total of 601 drug efficacy studies, conducted in 30 different countries since 1995 to examine the therapeutic efficacy of chloroquine, sulfadoxine-pyrimethamine, amodiaquine or chlorproguanil-dapsone (one study only) used as monotherapy, or to examine these drugs combined with each other, or combined with artesunate. The summary drug efficacy estimates took into consideration: 1) studies conducted before or after 2000; and 2) studies which used WHO standard efficacy testing protocol from 1996[137] or 2001[138] respectively, or studies which used another protocol. When data from only few studies on specific drugs or drug combinations were available, summary estimates were not made and only results of specific studies were assessed.

[137] Assessment of therapeutic efficacy of antimalarial drugs for uncomplicated falciparum malaria in areas with intense transmission. Geneva, World Health Organisation, 1996 (document WHO/MAL/96.1077).

[138] Monitoring antimalarial drug resistance. Report of a WHO consultation. Geneva, World Health Organisation, 2002 (document WHO/CDS/CSR/EPH/2002.17-WHO/CDS/RBM/2002.39).

## J. Limitations of the Research

Some of the reported studies were based on clinical failure rates (early treatment failure + late treatment failure), others were based on total failure rates (clinical failure + late parasitological failure), while some used both criteria. All reported results were included in the assessment. As part of the assessment, the proportion of studies reporting clinical failure rates above 15% and total failure rates above 25% on day 14 were indicated to reflect the desire to which the recommended WHO cut-off points for national drug policy change was exceeded in a country. When results from day 28 were reported, these were also considered in the assessment.

All available country-specific drug efficacy data were presented in country fact sheets together with the technical details on the grant agreement, the amount of approved funding and the types of drugs identified, the country's present treatment guidelines for first and second-line treatment, and any information on recent policy changes or transition toward policy change. These country fact sheets were made available to the participants prior to the consultation meeting of 2 May 2004 to allow participants time to review the data.

A confidentiality agreement was signed by meeting participants on the information presented during the meeting. Furthermore, a disclaimer from WHO was provided for the meeting. The recommendations made during the review meeting on which antimalarial drugs were appropriate for each country, together with some general recommendations, are presented in the following section.

## K. Research Findings and Recommendations

The recommendations from the review meeting were as follows: 11 grants were identified as countries already using ACT as first-line treatment, therefore no action was required; 8 countries were already in transition to the use of ACT as first-line treatment, therefore action was needed to reprogramme the grants; 5 countries were already in the process of policy change, i.e. with policy decisions already taken but pending implementation, therefore action was required to reprogramme the grants; 12 countries had not yet started the process of policy change, although available data suggested a need for change, therefore action was required to engage these countries into starting the process

as well as reprogramming the grants; 2 countries did not need to change because there were no available information to suggest that chloroquine were ineffective; 3 countries used combination therapy considered to be effective, but were recommended to view this treatment regime only as an interim solution while transitioning to ACT; and 3 other countries were identified as having *P. vivax* predominantly, therefore a change in treatment regime from chloroquine was not required.

The 44 grants reviewed were grouped according to the following categories: A) Countries already using ACT as first-line treatment; B) Countries in transition to use ACT as first-line treatment; C) Countries with *P. vivax*; and D) Countries that have not changed to ACT as first-line treatment,[139] The four groups of countries are as follows:

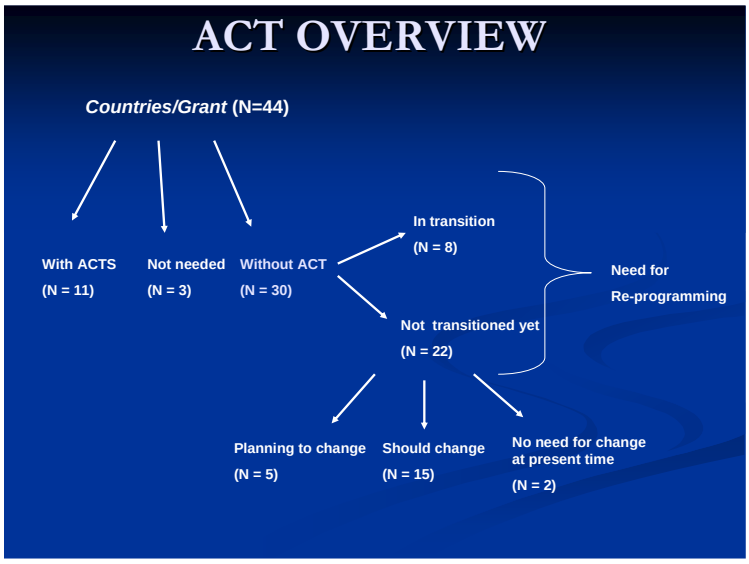



Figure 20: ACT Overview: Global Fund Partnership Forum Meeting, July 2004.
Source: Global Fund 2004

Discussions were not held for countries in category A, B and C. The discussions focused on the 22 countries in category D, so as to form a consensus on whether to recommend a shift to ACT as first-line treatment, given the available drug efficacy data. The outcome of the research findings was as follows:

1) Five countries (Democratic republic of Congo, Eritrea, Ethiopia, Madagascar and Uganda) were planning to shift from the conventional antimalarials used as monotherapy

[139] The detailed recommendations for all 22 countries in category D are listed in Annex 2.

to ACT, but have not yet transitioned. Recommendations were made to the Global Fund to encourage and support this change.

2) For twelve countries (Angola, Burkina Faso, Chad, the Gambia, Guinea, Malawi, Mauritania, Nepal, Niger, Nigeria, Pakistan and Somalia), evidence suggested a need for change from the conventional monotherapies. Recommendations were made to the Global Fund to encourage and support a change of first-line treatment to ACT or combination therapy in these countries and to reprogramme existing funding from the Global Fund.

3) Three countries (Mozambique, Rwanda and Senegal) have implemented the combination of amodiaquine (AQ) + sulfadoxine-pyrimethamine (SP) as first-line treatment, which can be used as an interim solution for some time; however, it was recommended that this treatment policy be seen only within the context of a process to change to ACT as first-line treatment, as resistance levels against SP and or AQ may have been evolving rapidly.

4) For Swaziland, efficacy data did not indicate a need to change, whilst acknowledging that there were limited available data.

5) For Haiti, no efficacy data were available; however, there were no other information suggesting a need to change of treatment policy. Routine testing of drug efficacy was recommended.

In summary, a total of 44 grants were examined which had an antimalarial component. The review excluded 11 grants already requesting ACTs, and 3 grants, which did not need a transition to ACT. The drug efficacy review focused on 30 country grants not using ACTs at that time. Haiti and Swaziland were excluded, as there was no need to change at the time of review.[140] Six countries were successful in obtaining additional funding for malaria in Round 4.

[140] Chad did not receive TRP recommendations. Indonesia was already on ACT.

## L. Specific Tools for ACT Reprogramming (Global Fund Secretariat Level):

Following the review, a process of reprogramming of malaria grants for the countries was initiated by the Global Fund. There was an agreement on mechanisms to ensure that updated information on antimalarial drug efficacy be considered in future funding decisions. Given the substantial changes in the planned targets and implementation activities associated with ACT reprogramming, special policies and procedures (i.e. additional performance-based funding instruments) had to be created and approved by the Board to accommodate the requirements for "significant reprogramming".

### A. Special Board approval to meet "significant reprogramming" of malaria grants:

At the Ninth Global Fund Board meeting held in Tanzania in November 2004, the Board approved "Significant reprogramming" issues in light of new scientific evidence (e.g. ACT) which served as impetus to the approval of new Board policies on "significant" or "material" reprogramming.[141]

The Board policy stated, "The approval was subject to a re-review by the TRP if, after consultation with the recipient but in the sole discretion of the Global Fund, changes in scientific evidence (as identified in collaboration with WHO and other technical partners) "materially" affect the proposal."[142]

For such a review, if the TRP recommend that, in light of the new scientific evidence, the approach taken in the proposal should be changed; the Board would reconsider the approval of the proposal. The PR would have the opportunity to submit a revised version of the relevant parts of the proposal to the Global Fund Secretariat and the TRP prior to the Board's decision.

The Board expanded the circumstances in which the Phase 2 decision-making process could be accelerated by modifying the existing decision on the Phase 2 process,[143] to read as follows: "The decision may be taken earlier in cases of: (i) accelerated

[141] Prior to the ACT reprogramming issue, there were only a few grants with significant reprogramming issues, namely financial related (i.e. due to exchange rate fluctuations).
[142] The Global Fund. Ninth Board Meeting. Decision Points. November 2004.
[143] as set forth in GF/B8/2, page 7.

implementation; (ii) severe exchange rate fluctuations; or (iii) additional financing needs resulting from changes in scientific evidence."

The Board also stipulated that changes recommended by the TRP should not substantively affect the goals, objectives, or strategy of the approved proposal. Any modifications to proposals that are made in light of changing scientific evidence that substantively modify the goals, objectives, or strategy of the proposal must be referred back to the Board for approval.

### B. Creation of a Pooled ACT Account:

In an effort to address the constraints in accessing ACT and implementing programmes, several modalities were under consideration including the transfer of funds allocated for drugs into a separate trust account at the World Bank, serving as the Trustee for the Global Fund. Funds would be earmarked for a country within the trust account and that participation in the pooled financing arrangement would be voluntary.

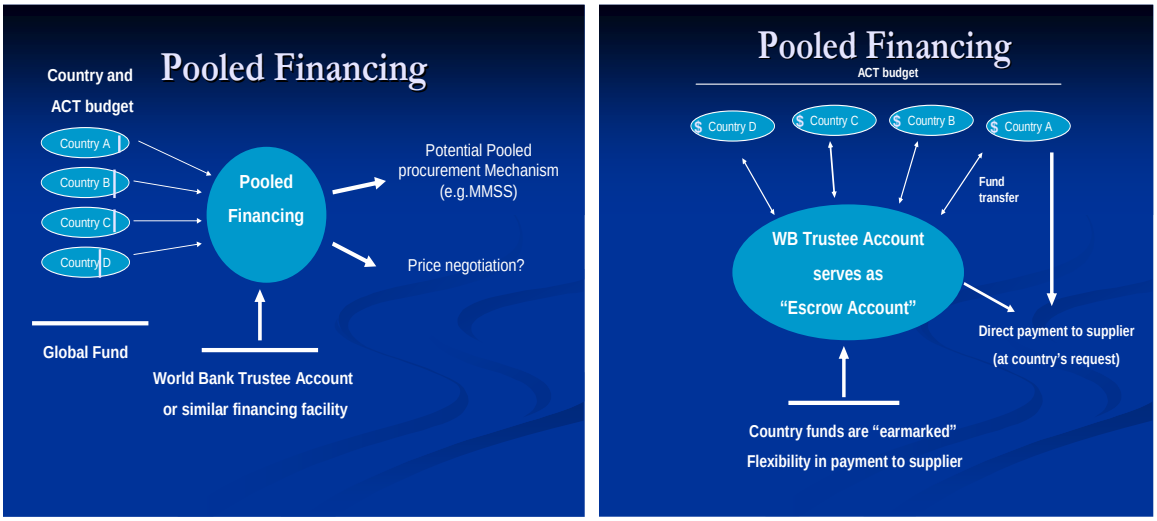



Figure 21: Pooled Financing. Global Fund Partnership Forum Meeting, July 2004.
Source: Global Fund 2004

The Pooled ACT Account (later renamed ACT Memorandum Account) was established to operationalise the June 2006 Board decision in order to accommodate the adoption of the switch to ACT. The ACT Memorandum Account was set up to serve as an account tracking mechanism, based on approved but uncommitted funds. The Board was

requested to approve USD 205 million which was allocated from: 1) approved but unsigned Round 4 proposals (i.e. estimated for ACT drug procurement within Round 4 grants estimated to be approximately USD 115 million); and, 2) Phase 2 special approval for ACT (i.e. USD 90 million) in order to track potential ACT expenditure by grantees. The account consolidates funds that may be used for ACT procurement where disbursements would not be made from this account but funds would be drawn down from the Memorandum Account from committed funds at the time of grant signing. As with any other disbursements, countries would be able to explore direct payment options to suppliers, but would not be used from the Memorandum Account. In essence, the creation of the Memorandum Account was to signal to manufacturers and suppliers regarding the pool of resources made available from aggregated funding for potential ACT procurement.

### C. Allocation of USD 90 million (accelerated funding from Phase 2):

The Board further made a decision in June 2004 authorising the Secretariat to commit up to USD 90 million to accommodate the transition costs associated with the switch to ACTs (part of the USD 205 million allocation of funds). The allocation was an interim measure to reprogramme 28 malaria grants financed by resources of Phase 2 funding, allowing the Secretariat to allocate extra funds to Phase 1 of programmes from the USD 90 million (i.e. effectively a concession that enables reprogramming to commence with allocation based on the relative need and programme readiness of countries). The USD 90 million funding allocation was made from the programme's Phase 2 renewal amount (i.e. an accelerated approval of a portion of Phase 2 funding).

### D. Collaboration with Technical Partners (Global Level)

Based on the analysis, the Global Fund Secretariat identified the following key elements for reprogramming: prioritization of countries according to grant and procurement status for review; brief FPMs on steps for reprogramming; inform relevant countries and partners; examine transition requirements for ACTs; closely collaborate with RBM Partners (e.g. Malaria Medicine and Supply Service); and, industry to ensure access to ACTs.

The Secretariat worked with UNICEF and WHO to consolidate the quantification of the demand for ACT and collaborated with RBM to assess technical support needs for reprogramming and rolling out of ACTs. The Global Fund coordinated training workshops in order to strengthen the procurement and supply chain management capacity of PRs in collaboration with the World Bank, WHO, RBM and other partners. The workshops were held in Nairobi and Addis Ababa in 2004, with a total of 29 countries participating at the workshops.

**RBM Partners** held PSM Plan Workshops to help countries to prepare their PSM Plans to "unlock" funds from the Global Fund with the following activities:

**Technical Assistance:** Training workshops were held for consultants to identify and train a pool of consultants able to support countries in procurement and supply chain management. A common database of consultants in supply management with HIV/AIDS was established and guidelines were released for treatment policy change through the stewardship of Management Sciences for Health (MSH). Direct country support was also provided by a number of partners (e.g. MSH/RPM+, UNICEF, etc.). Technical assistance was also provided to drugs manufacturers: 1 in India and 1 in China in 2005, 3 in Africa in 2006.

**Procurement:** information dissemination on forecasting was shared with manufacturers and procurement agencies (UNICEF, UNDP/IAPSO, IDA, WHO), document on Artemisia (cultivation, extraction, new sources and prices) and there were coordination efforts for assistance to countries (e.g. mapping needs and resources).

### E. ACT Quantification Exercise (Gap Analysis)

The Global Fund collaborated with partners to address forecasting ACT needs, quantification, pooled procurement and PSM issues. Based on the malaria grant reprogramming efforts, it was estimated that the drug gap for the 28 countries for transitioning to ACTs was approximately USD 400 million over a two-year period. In order for countries to accommodate the higher cost of ACTs, USD 250-300 million was expected to be covered through: ACT reprogramming within the two-year approved grants from Rounds 1-3; the remaining funds from Phase 2 renewal process; and funds

from Round 4 TRP approved proposals. Therefore, USD 100-150 million was identified as a funding gap.[144]

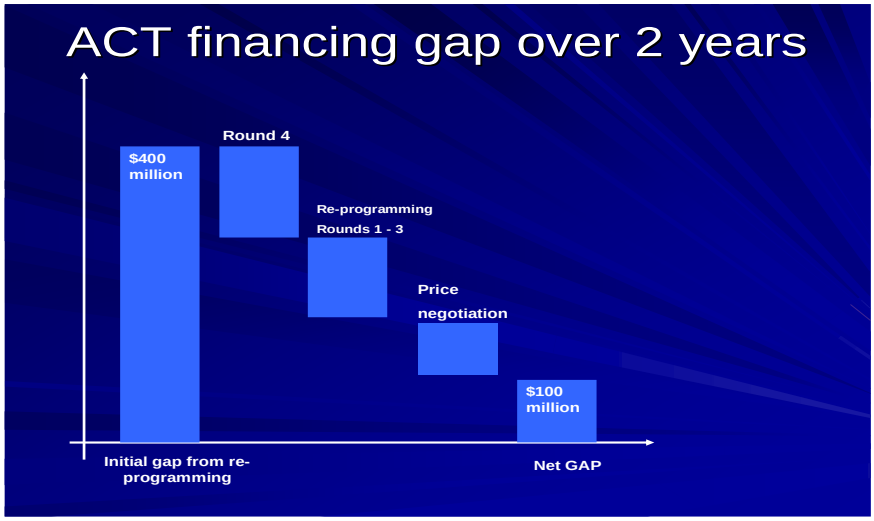



Figure 22: ACT Gap Analysis. Source: The Global Fund 2004

**Overall Malaria Funding Rounds 1-3**

| | 2 years | 5 years |
|---|---|---|
| Overall malaria grants (61) | $491 million | $959 million |
| Total budget for grants that need re-programming (30) | $320 million | $637 million |
| Drug budget for grants that need re-programming | $23 million | $49 million |
| Equivalent number of treatments | 284 million | 592 million |

Table: 3: Malaria Funding (Rounds 1-3). Source: The Global Fund 2004

## F. Methodology used for malaria reprogramming

Data included Rounds 1-3 approved malaria grants with allocated funds for procurement of antimalarial drugs. The assumptions for malaria reprogramming for the 30 countries were based on: 1) country specific assumptions; 2) treatment assumptions; 3) product assumptions; and, 4) financial assumptions.

[144] Global Fund Eight Board meeting, 30 June 2004. GF/B8/4. p 7.

1) **Country Specific Assumptions** included: grants which were already signed with procurement activity; grants already signed but with no procurement activity; and, grants that were not signed as yet.

2) **Treatment Assumptions:** ACT was assumed as first line treatment and the chosen drug was in accordance with standard WHO treatment guidelines. In addition, the following assumptions were used:

- Treatment was calculated for the same number of patients for ACTs (i.e. number of treatment assumed to be constant);
- Cost of treatment was weighted to include children and adults (based on population ratio and number of attacks);
- Where PR provided financial information for only year 1, the same level of treatment is assumed for grant lifetime;
- Where type of ACT was not specified, weighted average is used USD 1.39 (i.e. price of Artesunate+S/P at USD 1.21, Artesunate+Amodiaquine at USD 1.21 and price of Coartem at USD 1.76); and,
- The price of Artesunate+Mefloquine was not included in the weighted average (only used in a few countries at a treatment cost of USD 4.04).

3) **Product Assumptions:** Production estimates were made based on the assumption that antimalarial prices were maintained at the current level (i.e. CQ price at USD 0.06, S/P and Amodiaquine at USD 0.15)[145]. Other assumptions included:

- If S/P is specifically for IPT, allocated budget was not converted for ACTs;
- S/P is used, 10% was assumed for IPT;
- If CQ is used for *P. Vivax*, allocated budget was not converted for ACTs; and,
- If Quinine is indicated, allocated budget was not converted for ACTs.

4) **Financial Assumptions**: Budget calculations were based on 5 years and budget for drugs were obtained from proposals and, where available, from PSM plans.

[145] Whilst acknowledging that it may result in over estimation.

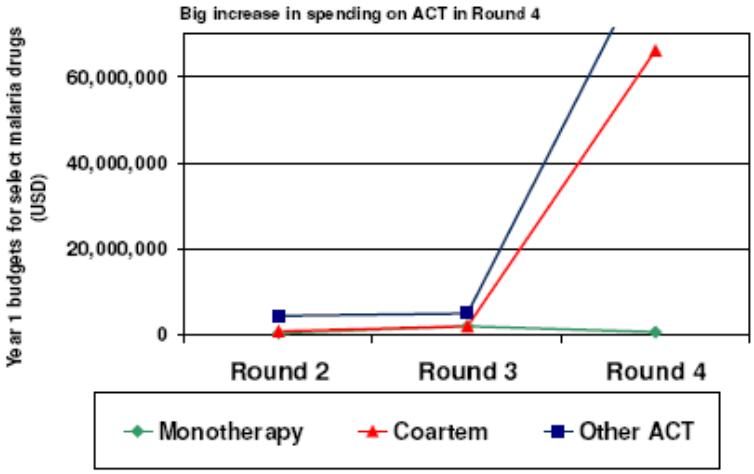



Figure 23: ACT spending (Rounds 2-4) 2004-2005. Source: Global Fund 2004

## G. ACT Production (Availability of ACTs)

The significant increase in the demand for ACTs from countries adopting the new ACT policy implied that there was an increase in demand for ACTs. According to WHO estimates, the global demand for ACT increased from a few hundred thousand in 2001-2002 to at least 120 million ACT treatment courses for 2006.[146]

As of December 2005, only one ACT (artemether/lumefantrine) or commonly known as Coartem produced by Novartis was pre-qualified for procurement by WHO. A single formulation of Artesunate 50 mg tablet produced by Sanofi-Aventis has also been pre-qualified.[147] Novartis entered into a special pricing agreement with WHO in 2001 and extended the agreement to UNICEF in 2004. Under the agreement, Novartis provided the drug at cost price for use in the public sector in malaria endemic countries. WHO, through a panel of experts, reviews requests for supplies of Coartem subsequently both UNICEF and WHO procures the drug for governments, UN and bilateral agencies, and non-governmental organisations.[148]

The role of partner institutions such as WHO, MSF and UNICEF were essential in forecasting demand for ACT taking into consideration that the production cycle for ACTs was approximately 9 to 12 months. At the Nairobi meeting, it was estimated that

[146] Facts on ACTs, RBM Info Sheet, January 2006.
[147] RBM: Procuring ACTs at preferential prices, p.1
http://www.rbm.who.int/docs/mmss/procuringACTpreferentialprices.pdf
[148] Ibid., p. 2

60 and 100 million ACTs was to be made available on the market in 2005 and approximately 250 million treatments were estimated for 2006. Countries were encouraged to play a key role in the market for ACTs, in order to stabilise the market by adopting ACTs. Some degree of volatility was expected in 2005 but it was thought that the market could have been stabilized by the collective stimulation of the market and proper planning for lead time. Therefore, data from the countries was urgently required and countries were encouraged not to stockpile ACTs given the short shelf life, but to "buy small and frequently".

MSF indicated that some suppliers were not in a position to guarantee price reduction or stable prices for 2005 and therefore there was the need to address long lead times. According to UNICEF, large orders could be made with fixed time deliveries, to avoid inefficient or small orders and to assist with price negotiation. Patent issues, reverse engineering, generic development and counterfeit products were also discussed. It was felt that manufacturers were moving towards cheaper labour markets and a strong market would generate additional suppliers.

### H. ACT Projected Availability (Forecasting and Quantification):

**The creation of Malaria Medicines and Supply Services (MMSS):** MMSS was set up in September 2004 within the Roll Back Malaria Partnership to provide services to countries to access quality antimalarial drugs and other essential supplies through collaboration with partner agencies, and to facilitate procurement and supply chain management efforts. The role of MMSS was to consolidate all ACT country forecasts, including anticipated demands from international funding institutions and procurement agencies and to widely disseminate available information to both manufacturers and health development partners.

MMSS focuses on five levels:[149]

i) **Forecasting:** MMSS complies, consolidates and establishes forecast for drugs and nets;

ii) **Supply/manufacturing:** MMSS worked with technical partners to proactively identify reliable commodities and supplies and facilitated technical assistance to manufacturers to accelerate the submission of pre-

[149] What is MMSS? http://www.rbm.who.int/docs/mmss/HandoutMMSS.pdf

qualification/certification and worked with partners to facilitate investment in manufacturing;

iii) **Procurement/order management**: MMSS assisted countries in preparing their procurement plans, and in identification of available product (i.e. quality assurance standards), managed the supply of items, tracked and maintained updates of procurement activities of various agencies, and maintained updates on production plans;

iv) **Transport/logistics:** MMSS assisted countries with estimating costs and identifying time constraints and solving logistic issues; and,

v) **Distribution/drug management:** MMSS fielded missions to review drug management situations and worked with partners to provide technical assistance to countries in drug management and distribution plans.

## I. Drug Registration:

WHO established a pre-qualification process of artemisinin on the basis of compliance with internationally accepted standards of Good Manufacturing Practice (GMP). Pre-qualification process is time consuming due to its rigorous and stringent process. WHO pre-qualification project is not an international pharmaceutical authority but works as an international body utilising technical experts from highly regulated countries to assess the quality and proof of evidence of generic products.[150] There are four stages to WHO pre-qualification of manufacturers of ACTs:[151]

i. **Preparatory Phase:** including drafting of specifications and guidelines (products and product files, and publication of expression of interest;
ii. **Document Review Phase:** including receipt of expression of interest (letters and files), screening, assessing and reviewing dossiers, and reports;
iii. **Plant Inspection Phase:** for GMP compliance, with team of inspectors appointed by Quality Assurance and Safety of Medicines/Essential Drugs and Medicines, inspections carried out jointly with respective drug regulatory authority; and,
iv. **Reporting Phase:** resulting in a “white” list of products and manufacturers.

[150] KIT Royal Tropical Institute, 2006. p. 48
[151] WHO: Global Malaria Programme. 2006. p.14

For approval of application, the pre-qualification process requires:[152]

- Chemical data (both active substance and formulating ingredients);
- Pharmaceutical data of the product: complete formula (including specifications), manufacturing processes (e.g. validation data), analytical and quality specifications of the end product, and method of analysis and assay of active ingredient in the end product;
- Product stability profile;
- Clinical data (i.e. safety and efficacy);
- Innovator products: full documentation of preclinical and clinical safety and efficacy according to guidelines of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, substantiate all claims on the summary of product characteristics; and,
- Multi-source products: demonstrated bioequivalence and direct evidence in support of safety and efficacy.

### J. New Research: Antimalarial products in the pipeline

At the Nairobi meeting, MMV indicated that the easy way to administer paediatric formulation is a near term solution and the paediatric (melt in the mouth) Coartem - a project under MMV might become available within a 2-to-3-year time frame. Similarly, a product for pregnant women was expected to be available after 2009. Some participants indicated that China has a good track record in producing antimalarials where Artekin is registered and is relatively cheaper than Coartem. However, there was not much data on safety aspects and it felled under the responsibility of the Ministries of Health at country level. Participants emphasised that local research & development was key in removing barriers. Although WHO approval is an indication to countries, it does not necessarily replace national drug registration and other procedures. In such cases, participants agreed that national decisions will have to prevail. Participants mentioned that some initiatives that are useful in advancing drug access such as – Initiative for Pharmaceutical Technology (IPTT) and the initiative by New Partnership for Africa's Development (NEPAD) in promoting technological transfer to African countries.

[152] Ibid., p. 15.

## K. Pooled Procurement Initiatives

**Global ACT Subsidy:** In early 2004, the Institute of Medicine (IOM) convened a meeting in London, UK to discuss antimalarial drugs and procurement of ACTs. In July 2004, IOM published a Report entitled *"Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance"* which highlighted the challenge of making effective antimalarial drugs widely accessible to the malaria affected populations due to the increased cost. The creation of a global subsidy for ACTs would make it available for approximately 10 cents per treatment, the cost of the old medicines.

The report proposed that a high global subsidy should be applied in the drug distribution chain, i.e. to buy the new drugs from manufacturers at competitive prices and then resell them at substantially lower prices to both public and private sectors distribution entities within malaria endemic countries. Under the committee's proposal, countries that receive subsidised antimalarials through the procurement system would be expected to monitor how well public and private drug-distribution channels deliver the drugs to those in need and should be required to track the emergence of drug resistance.

In November 2004, the RBM Board endorsed the IOM Report's conclusions of the need for Global Subsidy of antimalarial drugs and an international system for procurement of antimalarial drugs paving the way to set up an international system for procurement of ACTs.[153]

However, by April 2005, no agreement was reached for setting up an international system for procurement of ACTs. RBM Working Group on Financing and Resources meeting held in Washington in September 2005 decided to work on the architecture and financing of a global subsidy for ACTs. Thereafter, a small task force was set up to prepare a letter of intent (LOI), for submission to the Bill & Melinda Gates Foundation. The LOI was submitted on February 24 2006 with the objective to develop a detailed architecture and operational plan for a high-level global subsidy. In March 2007, a follow-up meeting was held in Amsterdam, Netherlands to discuss the mechanisms and rationale for a global ACT subsidy.

[153] As per Board sub-committee meeting 20 December 2004.

## L. Procurement and Supply Management issues

It was widely acknowledged by countries and technical partners as early as 2004 that in view of the adoption of ACTs and the potential disruption of the procurement cycle might well test the PR's institutional capacity with respect to their procurement and supply management planning.

The Global Fund's Procurement Policy on Quality Assurance relating to the purchase of single and limited source pharmaceutical products required: a) approval by WHO pre-qualification scheme; b) approval by a drug regulatory authority that participates in the International Conference on Harmonisation (essentially a "stringent" authority from a developed country); or, c) if there were less than two suppliers that met the criteria of 1 and 2 then the product can be procured from any supplier that was compliant with GMP. GMP ensures that products are consistently produced and controlled according to quality standards. The guidelines address all aspects of production from raw material, premises and equipment used, to the training and personal hygiene of staff. The guidelines were defined to minimise the risk involved in any pharmaceutical product that cannot be eliminated through testing the final product[154] and is in the process of applying for pre-qualification of regulatory approval from a stringent authority. If the above was not possible, then it can be procured from any supplier that manufacturer from a GMP-compliant site.[155]

## M. Collaboration at Country Level:

The Global Fund initiated the meeting in Nairobi in September 2004 to explain and assist the countries with the process for ACT reprogramming. The objectives of the Nairobi meeting were to: achieve a common understanding of ACT reprogramming; engage in discussions and planning using the Implementation Guide; and, to accelerate grant singing procedures. Expected outputs of the two-day workshop were to: 1) determine ACT requirements through a quantification exercise and revision of procurement plans (utilising the implementation guide developed by MSH/RPM Plus and other RBM partners); 2) estimate financial resources required for ACT

[154] KIT Royal Tropical Institute, 2006. p. 38
[155] Ibid., p. 48

reprogramming; 3) develop an implementation timeline; and, 4) plan for technical assistance requirements.

All the countries encouraged to reprogramme were invited to the workshop and representatives from 17 countries attended including Benin, Burkina Faso, Comoros, Democratic Republic of Congo, Ghana, Guinea, Kenya, Madagascar, Malawi, Mauritania, Niger, Nigeria, Pakistan, Rwanda, Somalia, Sudan (North and South) and Uganda. Eight countries were not able to attend (Angola, Cameroon, Eritrea, Ethiopia, Gambia, Mozambique, Nepal and Senegal).

The Global Fund made presentations to outline the requirements for ACT reprogramming including accelerated funding options and allocation of USD 90 million to accommodate transition costs associated with the switch to ACTs. Based on the objectives set out for the meeting, a common understanding was achieved for countries and partners on the reprogramming issue. During the workshops, countries were able to define ACT quantifications and planning as part of the process to identify further technical assistance requirements and to move towards grant signing. The following key issues were highlighted and discussed during the meeting.

### a. ACT Treatment Issues:

Country participants (Sudan, Pakistan, Niger, Benin, Uganda, Nigeria, Ghana, Kenya and DRC) made presentations based on recommendations from their respective technical partners (WHO, CDC, RPM Plus). The discussions covered the registration of ACTs with national authorities and the essential drugs list. ACTs were on the commercial market in countries and public versus private sector challenges need to be addressed. The discussion clarified the issue of the lead-time and the short shelf life of ACTs taking into consideration the issue of financing and securing of funds for large orders.

### b. Implementation Challenges:

Uganda mentioned the challenges related to developing an IRS policy; low access to treatment due to coverage; and, prompt treatment of ACTs at community level (i.e. treatment within 24 hours). As for Ghana, the challenges were linked to the current attitude towards compliance issues (e.g. Artesunate+Amodiaquine require 8 tablets a

day for 3 days). Patients were taking Artesunate as monotherapy and IEC campaigns were focused on educating people on Amodiaquine as well. Although the national policy referred to a 25mg dose, a dosage of 25mg was not available as manufacturers were producing 15mg tablets. It was also emphasised that the procedures for addressing pregnant women and combining therapy needed to be clarified. The participant from Pakistan indicated that new combinations needed proper clinical trials before they can be pre-qualified. Benin mentioned the challenges of applying lab diagnostics at the community level.

### c. Procurement and Supply Chain Management Issues:

Technical issues surrounding the pre-qualification process and the need to address interim capacity building measures were discussed (e.g. in Kenya, 1 out of 41 drug manufacturers were pre-qualified). There was a big gap in issues concerning GMP and there was recognition that countries needed to be working jointly with partners to find interim solutions. As of January 2005, the Global Fund required procurement of drugs from pre-qualified companies. Some countries expressed reservations concerning the expansion of manufacturing capacity and the issue of a single source supplier.

### d. Affordability of ACTs:

ACT price differential was identified as a major issue in the public and private sectors (e.g. private sector price for an adult dose of Coartem was USD 10 in Africa and USD 24 in Europe and USA compared to USD 2.4 in the public sector). Participants also acknowledged that the issue of pilferage exist in many countries. In an interview process as part of market analysis for global ACT subsidy, a Ugandan retailer commented, “you will find free Global Fund Coartem on sale by private clinics – and you can understand why when the retail price is like 15,000 schillings (equivalent to USD 8.50)”[156]

### e. Sustainability of Financing:

Countries (DRC and Zambia) raised the issue of cost recovery and sustainability. Niger stressed the need to share experiences from other countries using ACTs. Zambia

[156] Global ACT Buyer Subsidy: Market Analysis and Methodology Annex. p. 75

suggested that countries should be investing in laboratory diagnostics and other health systems services (HSS). Concerns were expressed stating that there were implications for cost recovery as they anticipated that the number of cases would decrease over time. Tanzania indicated that cost recovery depended on the country's policies on financing and that the government alone cannot sustain the needs which would affect the decision on changing to ACTs. Guinea considered that ACTs should only be given to those in need and that countries should reinforce diagnosis at country level. It was felt that the Abuja target will be difficult to attain particularly with the introduction of ACT. The countries expressed concerns citing that governments would not be in a position to finance the cost of ACTs. Cost recovery for all public health services could only be considered if it is highly subsidised. Kenya stated that the issue of sustainability was still not being addressed and that there was a need to have short-, medium- and long-term goals to work through a broader partnership arrangement.

The discussion focused on misconceptions regarding the mode of financing. Questions were raised including compensation for other Phase 2 programmatic areas, the long-term solution given the current board decision, clarification on whether the USD 90 million was additional Board approved allocation and the basis for the decision, impact on effective implementation based on budget reallocation at country level, and understanding the mechanism of the Global Fund's Memorandum Account. Countries were concerned about financial sustainability issues and stressed that reprogramming must guarantee additional resources beyond the current 5-year grants.

### f. ACT Transition Issues:

Countries and partners (e.g. DRC and Centre for Disease Control) indicated that the countries were facing complex challenges including the transition process, policy on implementation, funding availability and in implementation process taking into consideration geographic, and demographic factors. It was acknowledged that implementation timetable would vary from country to country based on the decision to change treatment guidelines and the pre-qualification process.

The question remained what needed to be done taking into consideration the international and national pressure to switch once countries commit to the transition

process. It was evident that countries felt an enormous responsibility for rolling out ACT in terms of policy implications, need, price, costs, and sustainability of funding.

### g. Monitoring and Evaluation Issues:

There was an acknowledgement by countries on the need to address monitoring and evaluation issues. At the time of the meeting, only four countries (Zambia, Tanzania, Burundi and Zimbabwe) had plans to conduct Demographic Health Surveys (DHS). In addition, investment in operations research (i.e. cost effectiveness and sustainability plan) was also cited as a priority.

### a. Challenges in ACT forecasting at country-level:

Technical partners identified challenges in ACT forecasting including: in-country quantification capacity (i.e. lack of experience leading to overestimation or underestimation); availability of drugs and countries switching between first or second line treatment; and procurement capacity and implementation including logistics, drug management capacity, health worker training, and pricing policy.

### b. Malaria treatment policy change, challenges and lessons learnt in Zambia

The presentation outlined an overview of the burden of the disease in the country. It highlighted the role of RBM as a technical partner and Global Fund as a financier in the strategic framework; the rationale for change and the steps put in place for implementation (training, IEC etc.); as well as monitoring and evaluation plans highlighting the importance of a multi-sectoral approach and partnership collaboration.

The discussion included mechanisms of removing CQ rapidly from the system (e.g. Burkina Faso). WHO raised concern about the low level of diagnosis each year indicated by Zambia and the process of selecting Coartem. Zambia indicated that social marketing was in place making it affordable for NGOs (both the private sector price and national price are USD 2.40 through a subsidy mechanism). However, there were some problems with the manufacturer and the fact that Coartem was not sold at profit during piloting phase.

### c. Implementation of artemisinin-based combination therapy in Zanzibar: Progress and challenges

The presentation focused on the means of introduction of ACT, highlighting the reasons, process of change, the implementation phase including monitoring the outcome, and challenges. Questions were raised regarding the issue of addressing the private sector; the practical experience of using the Global Fund to implement policies; ways in which Tanzania/Zanzibar achieved country coverage within a short period; and, the impact on parasitological reduction with respect to diagnosis.

### d. Meeting outcome and analysis

Feedback from the workshop session indicated that clarification was still required on Global Fund's accelerated financing of USD 90 million as well as on the procurement process, and the role of MMSS for coordination and providing guidance on the right policy decision. Some uncertainties existed with respect to countries being guaranteed funding from Round 5 and the issue of accessing USD 90 million. It was evident that countries were at various stages of the implementation process which required coordinated technical assistance.

The discussion highlighted country specific issues and the use of tools developed by the technical partners (template for TA support in changing process). The policy change in some countries needed clarity and would require feedback from the countries to provide clarity on TA requirements. Countries were still unsure of choosing between different products. There was a sense among countries that certain manufacturers were influencing countries related to drug choice.

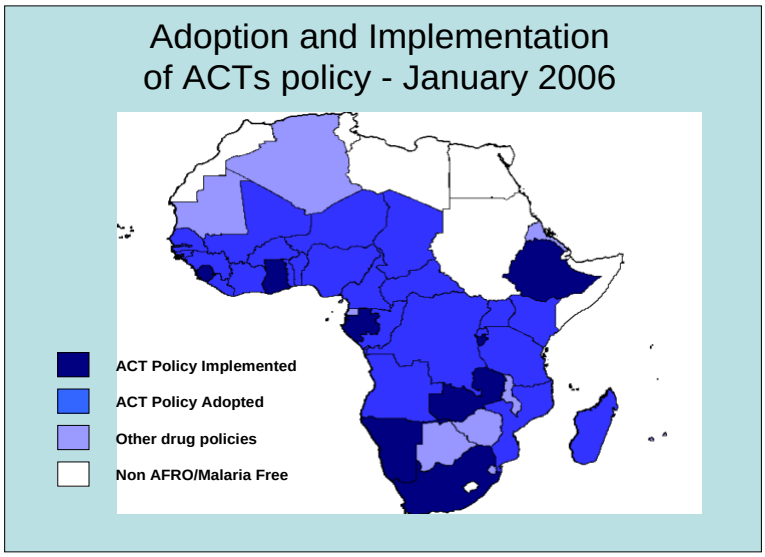



Figure 24: RBM Presentation. Source: Roll Back Malaria, May 2006

According to the RBM Secretariat, as of January 2006, 36 out of 46 endemic countries have changed drug policy to ACTs.[157] However, only 18 countries were deploying ACTs and only 4 countries (Burundi, Ethiopia, Zambia and Zanzibar) were using ACTs on a wide scale. ACT procurement increased significantly in one year. In 2005, 30 million doses of ACTs were procured compared to 4 million doses in 2004.[158]

The outcome of the malaria review process showed that only a small number of countries made a decision to immediately switch to ACTs. The transition was more gradual (refer to Figure 24) due to global and country level challenges described in Section VII.

[157] It should be noted that adoption of a national policy does not necessarily imply implementation of ACTs.
[158] RBM Secretariat presentation to RBM Board, May 2006.

# SECTION VII. CASE DISCUSSION

Several factors had significant impacts on ACT reprogramming at various levels including the Global level, within the Global Fund Secretariat level, and at the country level. The interaction between and within each of these levels affected ACT reprogramming efforts and further complicated the understanding and implementation of ACTs in the reprogramming process.

Challenges included: 1) coordination efforts at global and country levels; 2) global supply and demand of ACTs, procurement and supply management issues, 3) financing; 4) the outcomes of significant reprogramming;[159] and 5) systems effect at country-level.

## A. Coordination Efforts at Global and Country Levels

e. RBM Board/Secretariat Coordination and Restructuring Efforts (2005-2006)

The Roll Back Malaria Partnership was launched in 1998 by UNDP, UNICEF, WHO and the World Bank together with bilateral agencies, NGOs, research community, academia, foundation, private sector and malaria endemic countries. RBM's mandate is to: 1) raise awareness of the global malaria problem; 2) seek greater support for malaria control activities; and 3) support effective programmes in malaria affected countries.

The first phase of the RBM Partnership (1998-2002) focused primarily on advocacy particularly in Africa. During the second phase of the partnership (2003-2005), emphasis was on country support and the development of a global strategy. Sub-regional networks were also created (e.g. East Africa Regional Network, West Africa and Southern Africa Regional Networks), and together with other RBM partners, played an instrumental role in supporting countries to develop national strategic plans. At the same time, funding for malaria activities also increased substantially from approximately USD 60 million in 1998 to 600 million in 2005 in part due to the creation of the Global Fund, including funding through Round 4 proposals for ACTs.

[159] Refer to Section V on Performance-based Funding of the Global Fund.

In November 2005 at the RBM Partner Forum meeting in Yaoundé, Cameroon, the Board agreed to review existing structures of the RBM Partnership in light of the changing global climate to improve global implementation support and to scale up efforts to achieve impact. The “change initiative” took approximately one year starting from 2005-2006 and was approved by the Board in November 2006. The Change Initiative resulted in the formation of an RBM Executive Committee and 4 Board sub-committees and working groups: 1) Governance sub-committee; 2) Procurement and Supply Chain Management sub-committee; 3) Advocacy Working Group; and, 4) Harmonisation Working Group. The change Initiative made clear provisions on the roles and responsibilities of RBM Secretariat function and the roles and responsibilities of Partners.

The first meeting for the RBM Harmonisation Working Group took place in Dakar, Senegal in March 2006, with a mandate to coordinate and address malaria implementation bottlenecks at country level. However, the intensity and the high level of effort required for the restructuring of the RBM Partnership delayed the process of addressing the implementation challenges which was urgently required at country-level.

### f. Global Fund Coordination Efforts with Technical Partners

At the time the Lancet article was published, partnership collaboration and interagency collaboration occurred but at a very cautious pace given that coordination and communication issues had to be addressed in a politically charged and externally sensitive environment. Nevertheless, the malaria review process in April 2004 and the stakeholders meeting in May 2004 took place within a few months to reach a consensus on country resistance data and the way forward.

The Global Fund Secretariat worked with UNICEF and WHO to consolidate the quantification requirements in order to derive an estimate and projection for the demand for ACTs. The Global Fund also collaborated closely with the newly established Malaria Medicines and Supply Service (MMSS of the RBM Secretariat) to assist with negotiations with other partners to work on better forecasting and assess technical assistance needs for ACT reprogramming and roll out efforts. UNICEF agreed to consolidate the quantification of demand for ACT provided by the countries during the Nairobi meeting. UNICEF in collaboration with MMSS followed up with 50 countries requesting for ACTs to assess projected demands and global needs for 2005-2006. The collaboration efforts

helped with addressing global level demand issues; however, it was not sufficient to address the supply side issues.

### g. Global Fund Secretariat Coordination

Insufficient coordination within the Global Fund was another factor precipitated by turnover of key staff overseeing malaria issues within the Global Fund, impacting on the overall ACT reprogramming effort. After the Nairobi meeting in September 2004, there was a shift in focus from a dual-coordination function (i.e. operational considerations together with procurement considerations) to purely focusing on procurement and quantification functions within the Secretariat. The procurement focus alone was not adequate to address ACT reprogramming issues both at the global coordination and at country levels. Technical partners did not know who to contact within the Global Fund as the primary focal point for technical coordination post Nairobi meeting, held in September 2004.

In addition, staff turnover both at the technical and operational levels, including Fund Portfolio Managers resulted in weak internal coordination. The lack of a focal point with institutional memory and lack of continued engagement with new Portfolio Managers on longer term ACT reprogramming issues affected the decision-making processes of new FPMs which compounded the operational roll-out of ACTs at country-level (e.g. Comoros).[160]

### h. Country Coordination Efforts

Communications with countries (PR's & CCM's) were made via letters from the Global Fund Secretariat. However, the implications of ACT reprogramming were not understood by many of the recipients including the use of new instruments, resulting in reprogramming concerns and confusion (e.g. Benin, Comoros). There was a lack of understanding by countries on how to access USD 90 million from accelerated Phase 2 funding which required Global Fund Secretariat guidance.

[160] Refer to section on outcome of malaria review process on Comoros.

## B. Global Supply and Demand for ACT

WHO forecasted a global requirement of at least 120 million ACT treatment courses for 2006. It was estimated that the world market price for artemisinin was approximately USD 500-400/kg in 1999, decreasing to USD 200-300/kg in 2002. However, there was a threefold increase in artemisinin price in 2004 to USD 600-800/kg and was reported to have been as high as USD 1,100-1,300/kg reflecting a certain amount of market volatility. It was assumed that the market price would have stabilize at around USD 250/kg; however, it was widely acknowledged that there was no stable and predictable market in sight at that point in time.[161]

### a. Supplies of ACTs and Market Monopoly

Due to the ACT reprogramming efforts in 2004 including factors such as manufacturer's ability and willingness, country readiness etc., a global shortage resulted for ACTs. Suppliers and growers did not have enough lead time to grow sufficient quantities of Artemisia. Novartis' patent agreement with WHO meant that Novartis was the only pre-qualified supplier of ACT and several countries in Africa had already adopted Coartem as first or second line drug for the treatment of malaria. In addition, slow pre-qualification process for other potential suppliers, as well as slow production time, gave Novartis a market monopoly for a number of years.[162]

As of 2004, Coartem was registered in 77 countries worldwide and more than four million patients received Coartem treatment since 1998.[163] Under the special pricing agreement with WHO, the drug at cost price is USD 0.09 for infant treatment (i.e. children with a weight more than 10 kg) and paediatric formulation for infants less than 5 kg)[164] or USD 2.40 for adult treatment dose for use in the public sector.[165]

In 2004, Novartis quickly secured most of the artemisinin available on the world market in order to meet ACT demand (i.e. sufficient artemisinin derivatives for 30 million doses of Coartem treatment for 2005). Over half of this was to be produced during the last 3

[161] KIT Royal Tropical Institute, 2006. p. 30
[162] Monopoly defined by scarcity of raw materials and high retail prices.
[163] Novartis Media Release, December 22, 2004. p. 3
[164] KIT Royal Tropical Institute, 2006. p. 19
[165] KIT Royal Tropical Institute, 2006. p. 38

months of the year, which meant that the drug combination would have only become available after the high transmission season in many malarious countries.[166]

Novartis had also concluded agreements for supply of 11.6 tons of artemether by its Chinese partner Kunming Pharmaceuticals Corporation (KPC) and 15 tons of artemisinin by several other suppliers, most prominently Chongqing Holley. This was an amount sufficient to produce 60 million Coartem treatments. Final Coartem production in 2005 was highly dependent on the timely delivery of sufficient quantities of the key raw materials of artemisinin and artemether by Chinese suppliers who dominated the world market. Most deliveries to Novartis were expected to occur in the second half of the year, resulting in a production forecast of 30 million Coartem treatments in 2005.[167]

Novartis' market monopoly resulted in a great increase in the procurement price of raw materials. Subsequently, Artemisinin became a scarce commodity resulting in higher prices. The imperfect market conditions and the dysfunctional supply chain process clearly affected the availability and affordability of ACTs to patients in many malaria endemic countries. In addition, the lack of global supply of ACTs directly affected performance targets of many of the Global Fund malaria grants undergoing malaria reprogramming.

The retail price of ACTs also varied from USD 1.0 to USD 3.50 per treatment course.[168] In September 2006, there were price reductions in Coartem (i.e. approximately 30% decline in the cost of Coartem). This was mainly due to a decline in the cost of Artemisinin raw material, generic competition in the market, and achieving economies of scale.[169] The cost of adult treatment declined from USD 2.40 in 2004 to USD 1.80 in 2006-2007.[170]

In the long run, the availability of synthetic ACT might have led to market predictability especially if technical partners continued to assist with supply chain management issues leading to improved forecasting efforts at country-level. At the same time, the availability of synthetic ACT could also affect market dynamics for non-synthetic ACTs by influencing big pharmaceuticals to amass production control and possibly crowding out Artemisinin producers and growers in the market which would negatively affect local

[166] WHO World Malaria Report, 2006. p. 71
[167] Ibid., p. 1
[168] KIT Royal Tropical Institute, 2006. p. 17
[169] Global ACT Buyer Subsidy, March 2007. p. 30
[170] Ibid., p 39

production of artemisinin in countries. There was also a discrepancy between ACT availability in the private sector compared to that of the public sector. In order to address these various issues, the need for a global subsidised scheme was seen as an urgent priority by many partners.

### b. ACT Forecasting and Quantification

Forecasting and quantification would traditionally include the choice of treatment, coverage in private and public sectors, as well as budgetary considerations. In 2006, it was estimated that the global demand for ACT would reach 500 million treatments per year and the demand for non-synthetic ACT (i.e. artemisinin) would stabilise at approximately 100 million treatments per year with the assumption that an alternative treatment option (e.g. synthetic ACT) would become available on the market and is sold at similar prices.[171] ACT sales in the public sector had increased from approximately 200,000 treatments in 2001 to approximately 90 million treatments in 2006 but the market share was largely dominated by Novartis, despite the fact that ACTs remain a small share of the antimalarial market particularly in the private sector due to the high costs.[172]

### c. Drug Registration and Pre-qualification Process

The pre-qualification process had been slow compared to the demands generated for ACT supply. Hence, continued support to WHO pre-qualification process was required in order to reduce the length of time for potential manufacturers and suppliers to clear the WHO pre-qualification list. The increased number of manufacturers would encourage competition for supply of ACTs thereby reducing ACT prices.

### d. Procurement and Supply Chain Management Issues

At the time of ACT reprogramming period, there had been a lack of coordinated planning and purchasing including pooled procurement initiatives for ACT commodities. Some technical partners suggested that countries should buy in small bulks but frequently in order to cope with the production demands for ACTs. However, this type of procurement poses additional challenges for proper procurement planning which remains the most important component for development of a comprehensive procurement plan. Factors to

[171] KIT Royal Tropical Institute, 2006. p. 51
[172] Global ACT Buyer Subsidy, March 2007. p. 31

be taken into consideration as part of proper procurement planning would include drug transition issues which addressed phasing out of old drugs (e.g. drugs which are in the pipelines or on order, existing drugs in use, or availability of drugs sold in the informal sector etc.). Similarly, phasing in of new drugs would require proper forecasting and quantification, as well as addressing such issues as storage, logistics and transport, distribution and inventory management.

Coordination with global partners including MMSS and UNICEF and the time taken to compile forecasting and quantification information for ACTs during the initial reprogramming period coupled with Global Fund approval processes for PSM plans also contributed to the delays in procurement processes at country-level.

The establishment of Price and Quality Reporting Mechanism (PQRM) in 2004-2005 by the Global Fund was part of an attempt to help address ACT procurement needs by recipient countries.[173] PQRM is an electronic database where the PRs are requested to submit procurement information in order to improve the quality, completeness and use of procurement data shared amongst Global Fund partners in order to help address procurement bottle-necks during programme implementation.

### e. Pooled Procurement Initiatives

The pooled procurement effort which the Global Fund attempted to initiate in late 2004 and early 2005 based on demands generated by the private sector (e.g. manufacturers and suppliers) and by technical partners (e.g. WHO, IOM), did not occur due to internal policy constraints and failure to meet private sector expectations.

In April 2007, the Global Fund Board passed a decision to implement Voluntary Pooled Procurement Mechanism as a first step towards addressing market dynamics and to rapidly strengthen existing PQRM. The Voluntary Pooled Procurement Mechanism would cover a set of target products in a phased approach - initially targeting a small number of product categories, and would be operated by one or more procurement agents, which would be made available to PRs on a voluntary basis. As with standard Global Fund operating procedures, direct payment to suppliers (via procurement agent) from the Trustee account would be made, where the agent would enter relevant/required data in the PRM and make available, procurement capacity-building services and supply-

[173] The Price and Quality Reporting Mechanism was primarily initiated for ARVs.

chain-management assistance (via contracted providers), on an optional basis for all PRs participating in the pooled-procurement mechanism.

It was expected that the Voluntary Pooled Procurement Services would increase speed and reliability of the procurement process by decreasing lead times for delivery of products to countries, reducing stock outs, price volatility and negotiating better prices for larger quantities which would further reduce transaction costs for recipients, and ensue medium-term availability of commodities.

The activities for establishing a Voluntary Pooled Procurement service would include: conducting additional analysis to determine suitable product categories by end 2007; selecting and contracting appropriate procurement agent or agents by mid 2008; selecting and negotiating with manufacturers by end 2008 in order to fully operationalise the procurement model by early 2009. There were plans to contract with providers of capacity-building services and supply-chain-management assistance to be fully operational by July 2008.[174]

## C. Financing

### a. Sustainability of Financing:

During the Nairobi meeting in 2004, many countries (Rounds 1-3 malaria grants) expressed concerns over sustainability of financing based on existing funding and their ability to meet Global Fund's performance criteria. Since the ACT reprogramming initiative, new funding sources emerged and additional funding became available to malaria affected countries. Significant funding sources included Gates Foundation, the World Bank Booster programme (USD 500 million), US President's Malaria Initiative (PMI) USD 1.2 billion, and UNITAID (an international drug purchasing facility launched in 2006, which leverages on airline taxes for pharmaceutical procurement).[175] For FY 2007, US Congress appropriation totalled USD 257 million for bilateral malaria programmes including USD 161 million for PMI and USD 724 million for the Global Fund.[176]

[174] The Global Fund. Fifteenth Board Meeting Decision Point. April 2007
[175] UNITAID approved $52.5 million as an additional contribution to finance Round 6 Global Fund grants.
[176] Malaria Advocacy Working Group Paper, 12th RBM Board Meeting, p. 1.

In addition, countries now have the opportunity to apply through a new funding window called the RCC from the Global Fund for well performing grants. RCC would benefit malaria grants in the future if performance can be improved and sustained for the grants which were in the implementation stages.

### b. Global ACT Subsidy Initiative

Discussions on the need for ACT subsidy continued amongst concerned partners and other stakeholders through a series of global meetings based on the recommendations of the IOM report in 2004. The latest meeting was held in Amsterdam, Netherlands in January 2007 with a plan to launch an ACT subsidy fund for 2008.

The creation and the benefits of such a global mechanism was a subject of rigorous debate amongst experts and stakeholders. The process took four years from the time Global Fund made the radical call for the switch to ACTs, to the time required to build consensus on the need for a global subsidy scheme. As such, the subsidy initiative did not facilitate the ACT transition process for many countries requested to reprogramme.

## D. Outcomes of Significant Reprogramming

Significant reprogramming efforts spearheaded by the Global Fund, focused on the rapid creation of the Global Fund's special instruments (e.g. pooled financing, accelerated Phase 2 funding) in order to address the ACT transition process for countries identified during the malaria review process.

### a. Global Fund's Special Instruments

#### i. Pooled financing (ACT Memorandum Account):

The advantage of pooled funding would have been to provide greater security in the availability of funds to suppliers of ACTs to enable better forecasting and timely production of the required quantities of ACTs, and thereby achieving economies of scale. The supply of ACTs paid from the country's allocation would have been determined according to the procurement plan in terms of choice of ACT, quantity and delivery schedules.

The original intent of the creation of the pooled financing initiative (i.e. ACT Memorandum Account) was to initiate a pooled financing mechanism. However, at the time of the set-up, certain Board members questioned the Secretariat's attempt in creating – what was seen to be – a new separate operating account for the Global Fund. The Board's view that the Global Fund Secretariat was not mandated to hold an additional account altered the pooled financing approach. Instead, the Secretariat adapted a Memorandum Account to reflect the total amount of potential antimalaria drug for procurement in order to encourage manufacturers and suppliers towards increased ACT production efforts. However, the creation of the Memorandum Account was in itself insufficient for many of the private manufacturers. Manufacturers wanted the Global Fund to act as a guarantor for the procurement commitments made by countries and the Global Fund was not in a position to assume legal responsibility or bear the associated risk related to procurement on behalf of countries. The gap between private and public sector expectations as well as the reluctance of many countries to act on the switch to ACTs meant that the set-up of the ACT Memorandum Account became in the end, an ineffective instrument.

#### ii. Accelerated Phase 2 Funding (Allocation of USD 90 million)

The Global Fund Board meeting in June 2004 approved USD 90 million for reprogramming requirements for malaria grants. As a result of revision to the procurement plan and quantification requirements at the Nairobi meeting in September 2004, USD 65 million was provisionally committed to 15 out of the 22 reprogramming countries. Due to a number of factors (e.g. timeline, funding requirements etc.), Nigeria was the only country which availed itself to access funds from the allocation of USD 90 million. Acceleration of Phase 2 funds and the new flexible instrument made available by the Global Fund was in retrospect, an ineffective instrument for many countries earmarked for ACT reprogramming.

### b. Outcome of Malaria Review Process

#### i. Countries which switched to ACTs

From a total of 22 countries[177] which were requested to reprogramme in 2004, only 4 countries made an immediate decision to switch to ACTs; namely, Nigeria, Angola, Gambia and Somalia.

[177] This excludes 8 countries which were already in transition to the use of ACTs as first-line treatment.

Both Round 2 and Round 4 grants were not signed at the time of the Nairobi meeting for **Nigeria**. Round 4 grants were signed three months later in December 2004. At the time the Round 2 grant was signed, an implementation letter was issued so that the country could utilise Phase 2 funds from Round 2 for procurement of ACT. It was the first case where USD 90 million allocated funds were accessed for ACTs procurement.

**Angola** did not attend the meeting but the reprogramming efforts were led by the Fund Portfolio Manager and the documents and discussions were taken to country as part of grant negotiation process. Angola did not sign the grant at the time of ACT transition process and therefore it was easier for reprogramming effort. Angola accessed funding from Phase 2 as part of ACT reprogramming.

**Gambia** specified CQ in their grant. There was a WHO mission to the Gambia in 2004-2005 to assist the country with the reprogramming process (i.e. usage of funds for one-year transitional period from CQ to ACT) and to be in line with Global Fund requirements.

Follow-up on the countries which were requested to transition to ACTs showed that many countries in fact, did not transition to ACTs at the pace expected by the Global Fund. This could be attributed to a number of factors listed under the following categories:

### ii. Weak or lack of Communication and Coordination

**Benin** had two grants; one administered by UNDP, and one by AfriCare, an NGO which accessed funds through Phase 2 but not through accelerated Phase 2 funding window. This was mainly due to the fact that Benin did not fully understand the process for ACT reprogramming. The country was waiting for a letter from the Global Fund to inform them that they could access the money. The lack of clarity on policies and procedures at the Global Fund and PR level were also cited in the Grant Performance Report for Benin.[178]

Similarly, **Comoros** experienced changes in Fund Portfolio Managers and there was lack of information dissemination from the Secretariat to the country which became major factors in the ACT reprogramming efforts for Comoros. There were a number of months

[178] Global Fund Grant Performance Report on Benin.
http://www.theglobalfund.org/search/docs/1BENM_499_50_gpr.pdf

where there was no Fund Portfolio Manager assigned to the grant. In May-June, 2005, the PR and the CCM were informed of the option to "borrow funds from Phase 2" in order to access additional funds to procure ACTs and was encouraged to submit an application to exercise this action. According to the Grant Score Card, "the CCM and PR exhibited confusion in the understanding and execution of their respective roles and responsibilities, which has directly affected programme management and achievement of results. Additionally, the CCM failed to review and approved reallocation of funds requested by the PR and lack of communication to the LFA or the Global Fund Secretariat regarding procurement of health commodities."[179] As a result, there was no submission of application to borrow funds from the Global Fund Secretariat. In addition, when the new first line drug was adopted, it was not communicated to other stakeholders at the country-level (e.g. pharmacies, laboratories and other relevant entities).

**Senegal** did not attend the Nairobi meeting held in 2004 for ACT reprogramming and did not change from CQ. Moreover, under Phase 2 grant renewal process, Senegal malaria received a "No Go" from the Phase 2 Panel for Round 1 malaria grant due to poor achievement in treatment indicators, slow disbursements (i.e. 36% of grant funds), and challenges with coordination. In addition, the new Fund Portfolio Manager was not aware of the treatment component exemption under Phase 2. Had Senegal made the decision to switch to ACTs, it was likely that they would have been able to maintain a portion of the treatment funds related to ACTs.[180]

### iii. Short Grant Life Span

**Benin's** 3-year grant managed by UNDP was able to submit a CCM request to the Global Fund Secretariat. The Global Fund approved the 3-year grant to be extended by additional 5 months (i.e. a no cost extension of Phase 2 grant renewal process) changing the programme end date to 30 September 2006 in order to accommodate the late arrival of ACTs. However, the 5-month extension of the grant was not sufficient to address other difficulties associated with slow programme implementation including: human resource constraints at the sub-recipient level during implementation; and non-

[179] Global Fund Grant Scorecard on Comoros. http://www.theglobalfund.org/search/docs/2COMM_219_230_gsc.pdf
[180] However, Senegal was successful for Round 4 malaria grant to support the expansion of malaria programme.

availability of French speaking procurement experts which resulted in a delayed procurement process of commodities and subsequent implementation activities.[181]

**Burkina Faso** had a 2-year malaria grant. Burkina Faso came to the Nairobi meeting in 2004 to obtain information on the changes in drug policy. Subsequent to the meeting, the country changed their drug policy to ACT, using Coartem as first line drug and ART+Amodiaquine as second line drug reprogramming their Phase 1 grant with a view to purchase ACTs. However, due to the global supply shortage, they were not able to get the drugs in time before the end of their grant. In addition, since the grant signature for Phase 1 is for a two-year period, they were not in a position to access Phase 2 funds due to the short grant lifetime.

**Chad** had a three-year grant and decided not to procure drugs but to focus on ITNs. Therefore, the country did not access the funds.

### iv. Reluctance to Change National Drug Policy

National drug policy and treatment issues are important operational and technical issues which have an impact at country-level. In-country stakeholder agreement regarding the need to change treatment regime as well as the availability of appropriate dosage and time to monitor adverse effects needed to be taken into consideration. The analysis based on the Nairobi meeting showed that there were many countries reluctant to change (e.g. Malawi, Mauritania, and Madagascar) and countries voiced their concern regarding the lack of infant formula and safety issues for risk groups.

For **Madagascar,** Institute Pasteur, an in-country partner, expressed a different opinion regarding the change of treatment policy. Subsequently, Madagascar delayed their decision on treatment policy. There was a change in treatment policy in connection with procurement of RDTs for diagnoses of ACTs.

**Malawi**[182] did not reprogramme the grant since they did not want to change the drug policy. Instead, Malawi opted to remove the drug component from the Global Fund grant and sought funding from other donor sources.

[181] Global Fund Grant Performance Report, Burkina Faso, http://www.theglobalfund.org/search/docs/2BURM_204_204_gpr.pdf

[182] Malawi had switched from CQ early on rational evidence-based policies.

**Mauritania** attended the Nairobi meeting. However, the Ministry of Health decided not to switch to ACTs until additional scientific evidence was obtained and due to the fact that Mauritania had a small grant component. Mauritania was fortunate to secure funding from Round 6, and it was in the process of transitioning to ACTs.

### v. ACT Implementation already in progress

**Mozambique** had two malaria grants - one under the medical research council, with an ACT component, was already using ACT as part of the KwaZulu Natal (Lumumba) Project. ACT was used as second line treatment and was part of a small initiative. As a result, Mozambique did not need to reprogramme.

**Ethiopia** was already using ACTs and did not attend the reprogramming meeting. Ethiopia updated their ACT estimates for funding under Round 2. Ethiopia was treated as a special case since they were receiving other donor funding for procurement of ACT and therefore the funding requirements from the Global Fund grant for ACT reprogramming was small.

Shortly after the Nairobi meeting, **Ghana** immediately responded by revising their workplans and budgets. The Round 2 malaria grant was not going to be reprogrammed for procurement of drugs, rather the portion of malaria drug funds were to be redirected to health systems strengthening to prepare for rolling out ACTs under their Round 4 grant. The country was under the impression that they could access the funds for immediate procurement of ACTs. This did not occur due to the fact that the Round 4 grant was not effective at the time the order was placed. The grant was signed 3 months after the Nairobi meeting and the country requested direct payment to supplier (WHO) which accelerated the procurement and delivery time frame of ACTs.

Ghana initiated the change in treatment protocol from CQ to Amodiaquine+Artesunate in 2003, which became effective in May 2004. Stakeholder meetings were convened in 2002 but took two years for the intersectoral task team to develop a draft policy after assessment of studies on cost-effectiveness, side effects, cost to the patients and health system. Ghana then established multi-agency sub-committees, developed a detailed implementation plan, conducted sensitisation seminars including health staff, local drug manufacturers, media and the general public.

Due to its proper coordination and planning, Ghana was one of the few countries able to achieve or surpass its targets with a strong overall performance (lessons learned from ACT reprogramming of Ghana is outlined in Annex 9). According to the Global Fund's grant performance report, Quarter 8 results showed 276% achievements in IPT targets at the end of March 2007, and all impact indicators indicate improvements in morbidity and mortality of malaria among children under five years of age and pregnant women recorded at health facility level.[183]

**Kenya** was enthusiastic about ACTs and was the first country to revise their workplan by merging Round 2 and Round 4 workplans. Kenya was able to do this before the meeting because they realised that Round 4 included ACT treatment. Kenya did not need to accelerate Phase 2 of Round 2 since Round 4 grant was already effective and they were able to access funds from Round 4. The country, however felt that there was pressure from the Global Fund and other technical partners "forcing" them to switch to ACTs (e.g. Kenya requested to see the minutes of the meeting).

**Democratic Republic of Congo (DRC):** Changes in treatment policy for DRC took place prior to grant signature in September 2004 before the Nairobi meeting. The malaria grant covered 119 of the 515 health zones with ACT treatments. The country had already submitted revised estimates taking into account the use of ACTs. Approximately 1.7 million treatments were ordered in December 2005. However, due to a sub-recipient overestimation of drugs, there was a low consumption of ACTs. DRC also faced other challenges including supply chain management issues (e.g. inventory control, monitoring and reallocation of existing stocks), transportation, delayed distribution, training and IEC issues. Health workers and physicians were also not aware that the new treatment protocol was already in place.[184] The Global Fund procurement team visited DRC in 2006 and requested the country to relocate the existing drugs to other health zones.

### vi. Limitation of Grant Size

The **Comoros** grant was approved in 2004 and malaria treatment policy was changed to Coartem (artemether-lumefantrine) as first line treatment. Due to the increase in price, the country discovered that the original drug budget was insufficient to cover the

[183] Global Fund Grant Score Card, Ghana, GHN-202-G03-M
[184] Information Sheet on DRC, September 2006.

cost of drug procurement. Comoros only had USD 42,000 in the budget to buy CQ in the proposal. Comoros decided to purchase ACTs for USD 42,000 without proper consultation with the Global Fund. After the procurement and delivery of ACTs, the country was unable to utilise the drugs due to concerns regarding demand creation and unrealistic expectations of the public sector. The total lifetime budget was also too small (approximately USD 1.5 million) for the country to adequately address reprogramming issues.

The Grant Score Card for Comoros indicated that the programme experienced a shortage of antimalarial drugs due to a change in drug policy. Although Coartem was received by the country in November 2004, the introduction of Coartem did not start until July 2005. A delay in the finalisation of national drug policy which included cost-sharing agreements caused some delays in finalisation and subsequent distribution of Global Fund financed Coartem in the public sector health facilities.

As a result, Comoros showed underperformance in 6 of the 11 indicators with poor performance in each of the level 3 indicators. There was little evidence of programmatic improvement during the last 6 months prior to Phase 2 submission. The Global Fund Secretariat considered a “No Go” recommendation but allowed the CCM an opportunity to respond to the issues raised in the Phase 2 review process.

The malaria grant for **Guinea** was also small for reprogramming and based on performance of the grant at that time as well as institutional constraints at country-level, the country took a decision not to reprogramme the grant.

**Rwanda** attended the Nairobi meeting and revised the estimates but never requested any funds. The country took into consideration financing requirements and found that the current MOH budget was not sufficient to support the cost and implementation of ACTs. Rwanda decided to retain the current treatment of Amodiaquine+S/P and procured approximately 3 million treatments with the funds from Round 3. Following WHO recommendation and consensus from RBM partners, the Round 5 proposal which was signed in February 2006, reflected a change in first line treatment to Coartem implementing ACT scale up only in 2006.

### vii. Problems with Performance-based Funding Framework

**Niger** had a three-year malaria grant and wanted to utilise all of Phase 2 funds for procurement of ACTs however, questions were raised regarding measurement of performance-based funding if all the funds in year 3 were required for procurement of ACTs. A letter was sent from Fund Portfolio Manager to the country; however, the country made a decision not to reprogramme.

**Somalia** changed its first line treatment from CQ to ACT in 2005. However, the country faced some reprogramming challenges switching from CQ to ACTs without reducing the targets. Somalia was unsuccessful in its Round 5 proposal application but received approval for Round 6 only in October 2007 allowing the country to continue with its ACT implementation activities.

### viii. Implementation Challenges and Procurement Delays

**Nigeria,** was one of the 4 countries which transitioned to ACTs using accelerated Phase 2 funds at the time of reprogramming. The country had also undergone ACT implementation challenges. Nigeria was not able to reach its planned ACT treatment indicator for Round 2 malaria grant which stood at 14% for Quarter 6. Progress was only achieved at Quarter 8 reaching 92% of planned target for ACTs. Similarly, Round 4 malaria grant experienced procurement delays for health products during Quarter 3 and subsequently there were no financial expenditure for Quarter 3 (i.e. February 2005-April 2005). At Quarter 4, there were no progress recorded against planned indicators and in Quarter 5, ACT treatment only reached 8% of target. ACTs were only delivered in March 2006, which facilitated good progress in treatment indicators for Quarter 8.

In the case of **Pakistan**, although Pakistan had *P. vivax* as the dominant case, Pakistan used ACTs for their Round 3 grant. The Round 2 malaria grant received a NO GO for Phase 2 for not being able to achieve Phase 1 targets due to slow performance and fund utilisation (i.e. less than 10% of grant funds were utilised in December 2004). In addition, the Grant Performance Report also cited long PSM plan preparation and approval process. Procurement delays were also cited as hampering programme performance and implementation. Pakistan received Round 3 – a two-year malaria grant in January 2005 where ACT treatment was being implemented. The programme had a slow start; GPR reported treatment of patients with ACTs only at 6%.

Round 3 proposal for **Angola** indicated the use of Amodiaquine and S/P, and Angola switched to ACTs when the grant was signed in February 2005. However, according to the Grant Score Card, "the lack of an adequate PSM system during Phase 1 contributed to the most significant shortcoming in Phase 1 of the malaria programme (i.e. malaria treatment). The programme was unable to prepare quantification requirements and the funds were disbursed only in August 2005 for procurement of ACTs by WHO (as sub-recipient). The drugs arrived in late 2005 but it was only in May 2006 that the programme developed a distribution plan. These drugs were distributed later in the year and usage commenced.

North **Sudan** shifted to ACTs, which were procured and distributed in Quarter 3 to health centres and distribution to patients occurred in Quarter 4. A number of implementation challenges including global ACT shortages affected performance of the North Sudan grant including level 3 people reached indicators of malaria in pregnancy. The grants managed in South Sudan, showed better performance (e.g. 59% of targets reached for IPT amongst pregnant women).

**Uganda** changed to ACTs but faced implementation delays. According to the Round 2 Grant Performance Report, programme implementation was delayed due to: a) the late set-up of the programme Management Unit (PMU); b) the late appointment of the Third-Party Procurement Agency, and, 3) late approval of the procurement. This was compounded by the suspension of Global Fund grants to Uganda for two and half months in August 2005. The subsequent change in the PMU resulted in a loss of momentum which affected grant implementation. Post-suspension, the Ministry of Finance, as the appointed PR, was cautious in the implementation process and the Ministry of Health did not play a leading role in grant implementation. On lifting the suspension, an aide memoir was signed with certain agreed upon actions to be achieved by the PR and CCM. This included the recruitment of a Third-Party Procurement Agent, revision of work plans and procurement plans, in order to address the delays due to the suspension. With Round 4 funding, which focused exclusively on procurement of ACTs (80% of grant funds), the country was able to initiate procurement through WHO.[185]

[185] The Global Fund grant performance report, http://www.theglobalfund.org/search/docs/2UGDM_287_218_gpr.pdf

### ix. Misclassification and Site-specific Implementation

For **Eritrea,** the dominant case of malaria was *P. vivax* and not *P. falciparum* and was misclassified in the ACT reprogramming list. Eritrea therefore did not engage in any ACT reprogramming efforts.

The Global Fund invited **Cameroon** to attend the meeting but the country did not attend the meeting and there was no ACT in the budget. The proposal only included S/P for pregnant women only and therefore, the Global Fund was not in a position to request the country to reprogramme the grant.

**Nepal** did not switch to ACTs due to the fact that the dominant species of malaria was *P. vivax* and not *P. falciparum*[186] but experienced implementation delays from procurement bottlenecks. In order to help accelerate and effectively address implementation challenges, a second PR was selected for Phase 2 in December 2005.

**Indonesia** was included in the list since they were transitioning to ACTs but the country was utilising ACTs for selected districts implemented on a province-by province basis in accordance with specific drug resistant pattern. Indonesia therefore did not undergo major ACT reprogramming.

## E. Performance-based Funding on Malaria Grants

### a. TRP and Round 4 malaria proposals

After the malaria grant review meeting, all country fact sheets and recommendations were made available to the Technical Review Panel (TRP) of the Global Fund for use as reference during the review of Round 4 proposals, on 3-14 May 2004. As a result of the ACT review efforts and increasing awareness amongst TRP members, malaria proposals benefited from Round 4 funding.[187] Budget allocations for Coartem and other ACTs increased from USD 3.9 million in Round 2 to USD 89.9 million in Round 4, where the cost of drugs accounted for 54% of all approved funding for malaria.[188,189]

[186] Nepal Country Profile**.** http://rbm.who.int/wmr2005/profiles/nepal.pdf
[187] It was envisaged that Round 4 funding would go towards HIV proposals due to the new 3 by 5 initiative.
[188] The Global Fund, TERG 5 Year Evaluation, Evaluation Brief no. 4., page 8.
[189] This increase is exclusive of Rounds 1-3 malaria grants ear marked for reprogramming.

The Global Fund's Partners for Impact Report indicated an acknowledgement that malaria grants were slow in their first phase of implementation due to procurement and global supply issues for ACT treatment as well as for long lasting insecticide treated nets. The lack of programmatic progress and achievement for malaria during 2004-2006 were evident by the fact that an improvement in results were gradually witnessed only in 2006 with an increase from 60% to 73-77% after Phase 2 evaluation.[190]

### b. Performance of malaria grants review process (R5 and R6)

The success rate for malaria grants was cited as being the lowest for Global Fund Round 5 and Round 6. One of the main reasons cited was a global supply shortage of commodities including ACTs, many countries were not able to show a number of important treatment coverage indicators. The TRP reviewers take into consideration, past performance of Global Fund grants. The challenges faced by many countries, which were to a certain extent, due to external factors (e.g. ACT reprogramming efforts, global supply shortage of commodities), directly affected the success of future rounds of malaria grants.

This was also reflected in the performance monitoring and evaluation tool of the Global Fund top 10 service indicators. Level 3 indicators - also known as "people reached indicators" (see Annex 3) are the most highly weighted indicators during the performance evaluation process (e.g. Phase 2 grant renewal process). There are two main indicators related to malaria (i.e. number of ITNs distributed and number of people receiving antimalarial treatment). Other attributable indicators include number of people benefiting from community-based programmes and number of service deliverers training.

The Global Fund's mid-term and impact evaluation focused on three main level 3 indicators, i.e. people on ARV, DOTS detected for TB patients, and ITNs distributed. It was evident that the Global Fund was not able to utilise treatment indicator in order to capture treatment numbers for malaria and had to use a prevention indicator such as ITNs for its mid-term evaluation.

The success rate for malaria grants can be seen in a comparison table (refer to Table 4) for Rounds 2-6 proposal application process.

[190] The Global Fund. Partners in Impact, 2007. p. 47.

| | Country | Round 2 | Round 3 | Round 4 | Round 5 | Round 6 |
|---|---|---|---|---|---|---|
| 1 | Angola | | M | | M | |
| 2 | Benin | | M | M | M | M |
| 3 | Burkina | M | | M | M | M |
| 4 | Cameroon | M | M | | M | M |
| 5 | Chad | | M | | M | M |
| 6 | Comoros | M | | | M | M |
| 7 | Congo (DR of) | M | M | | M | M |
| 8 | Equatorial Guinea | M | | M | M | M |
| 9 | Eritrea | M | | | M | M |
| 1 | Ethiopia | M | | M | | M |
| 1 | Gambia | | M | | | |
| 1 | Ghana | M | M | M | | M |
| 1 | Indonesia | M | | | M | M |
| 1 | Kenya | M | | M | M | M |
| 1 | Madagasca | M | M | M | M | M |
| 1 | Malawi | M | | | | M |
| 1 | Mauritania | M | | | | M |
| 1 | Mozambique | M | | | M | |
| 1 | Nepal | M | | M | M | M |
| 2 | Niger | | M | M | M | M |
| 2 | Nigeria | M | | M | M | M |
| 2 | Pakistan | M | M | M | M | M |
| 2 | Rwanda | M | M | | M | M |
| 2 | Senegal | | | M | M | M |
| 2 | Somalia (Non-CCM) | M | M | | M | M |
| 2 | Sudan N | M | | | M | M |
| 2 | Sudan S | M | M | | | M |
| 2 | Uganda | M | | M | M | M |

**Recommendation**

| | |
|---|---|
| | Category 1 Recommended with little or no clarifications |
| | Category 2 Recommended with some clarification (funding priority over 2B) |
| | Category 2B Recommended with some clarification |
| | Category 3 Not recommended for funding but encouraged for resubmission |
| | Category 4 Not recommended for funding |
| H/T/M | Eligible but did not apply |
| | Ineligible from Round 6 |
| | CCM Non Compliance |

M Malaria

Table 4: Malaria Proposal Success Rate (Rounds 2-6). Source: Global Fund 2006

There were 22 out of the 28 countries which applied to Round 5; of which 4 countries (14%) were successful in their proposal application to the Global Fund. One country (Guinea) succeeded through an internal appeal process where the TRP reversed their decision. Seventeen of the proposals were marked Category 3 and one was marked Category 4. Similarly, for Round 6, of the 24 countries which applied, 6 countries (25%) were successful in securing Round 6 funding. Sixteen countries received Category 3 and 2 countries received Category 4 ratings. Angola's proposal was screened out for CCM non-compliance and was not submitted to the TRP for review. For both Rounds 5

and 6, there was an 80% failure rate for all the malaria proposals submitted by the countries earmarked for reprogramming.

### c. Performance of Global Fund malaria grants earmarked for reprogramming:

At the country-level, the majority of Global Fund grants which were earmarked for reprogramming suffered from reaching planned targets. According to a review of available Global Fund Grant Performance Reports and Grant Score Cards for the 26 countries,[191] 17 of the 26 countries (65%) showed poor performance indicators as shown in the table below:

| Country | Performance Indicators (underperformance) | Level 3 – People reached indicators Rating/Percent of Planned Target | Implementation Delays |
|---|---|---|---|
| Angola | 5 out 13 indicators (7%-77%) | Prompt and Effective Treatment (C)<br>Malaria in pregnancy (C) | Lack of PSM system during Phase<br>Procurement and distribution delays |
| Benin<br>(Round 1) | 8 of 18 indicators (0%)<br>1 of 18 indicators (33%) | 3 treatment indicators (B1) | |
| Burkina Faso<br>(Round 2) | 2 of 14 indicators (<50%) | 5 of 8 indicators exceed targets | |
| Cameroon<br>(Round 3) | 2 of 12 indicators (0%) | Malaria in pregnancy (131%)<br>No treatment no. | Procurement delays |
| Comoros<br>(Round 2) | 6 of 11 indicators<br>(12%-60%) | Pregnant women (25%)<br><br>Uncomplicated cases treated (55%) | Procurement delays<br>Coartem stock-out<br>Delays in change of drug policy |
| DRC<br>(Round 3) | 10 of 15 indicators (18-74%) | Heath Centres with drugs (25%)<br>Treatment (29%) | Procurement delays |
| *Eritrea<br>(Round 2) | 3 of 12 indicators (0%)<br>5 of 12 indicators (17-75%) | Home based malaria treatment (>80%) | Implementation delays |
| Ethiopia<br>(Round 2) | 7 of 18 indicators (0%)<br>5 of 18 indicators (17-75%) | Cases diagnosed within 24 hours of onset (18%)<br>Uncomplicated cases treated with ACTs (0%) | Procurement delays |
| *Gambia<br>(Round 3) | 1 of 21 indicators (0%) | Patients receiving correct diagnosis and treatment (111%)<br>Malaria in pregnancy (384%) | Strong programme management<br>Strong political commitment |
| *Ghana<br>(Round 2)<br><br>Ghana<br>(Round 4) | 0 of 11 indicators<br><br>1 of 12 indicators (52%) | Malaria in pregnancy (A)<br><br>Malaria in pregnancy (A)<br>Prompt and Effective Treatment (A) | <br><br>Exceptional performance |
| Guinea<br>(Round 2) | 16 of 22 indicators (<45%) | 6 indicators (0%) | Procurement delays |
| *Indonesia<br>(Round 1) | 6 of 23 indicators (0%-80%) | Uncomplicated cases treated with ACT (100%)<br>Uncomplicated cases treated with Non-ACT (138%) | |
| Kenya<br>(Round 2) | 5 of 16 indicators (0%) | Malaria in pregnancy (B2) | Procurement delays and set up of Procurement Consortium<br>Appointment of Financial Management Agency |
| Madagascar<br>(Round 3) | 3 of 14 indicators (<34%) | Home based treatment (B2)<br>People receiving anti-malaria treatment (0%)<br>Malaria in pregnancy (34%) | |
| Malawi<br>(Round 2) | N/A | N/A | Implementation difficulties within a SWAP environment |
| Mauritania<br>(Round 2) | 9 of 23 indicators<br>(<43% - 79%)<br>2 of 23 indicators (0%) | Prompt and Effective Treatment (B1)<br>Malaria in pregnancy (B1) | Procurement delays |

[191] Chad and Malawi were excluded from the review. Chad did not reprogramme and Malawi had no progress indicators.

| Country | Performance Indicators (underperformance) | Level 3 – People reached indicators Rating/Percent of Planned Target | Implementation Delays |
|---|---|---|---|
| *Mozambique (Round 2) | 2 of 10 indicators (<50%) | Prompt and Effective Treatment (B1) | |
| Nepal (Round 2) | 9 of 13 indicators (0%-13%) | Prompt and Effective Treatment (B2) | Procurement bottlenecks<br>Inadequate procurement expertise |
| *Niger (Round 3) | 2 of 13 indicators (<17%) | Prompt and Effective Treatment (B1) | Successful change in drug policy |
| Nigeria (Round 2) | 4 of 9 indicators (36%-62%) | Uncomplicated cases treated with ACT (36%)<br>Malaria in pregnancy (62%) | Slow procurement<br>Delays with ACT |
| Nigeria (Round 4) | 3 of 12 indicators (13%-67%) | Uncomplicated cases treated with ACT (13%)<br>Home based malaria treatment (100%) | Procurement delays<br>Delays with ACT delivery |
| Pakistan (Round 2) | 9 of 10 indicators (0%-42%) | Uncomplicated cases treated (25%) | Procurement delays<br>Long PSM plan preparation and approval process |
| Pakistan (Round 3) | 7 of 14 indicators (0-69%) | Uncomplicated cases treated with ACT (6%) | |
| *Rwanda (Round 3) | 13/33 indicators (0%-75%) | Prompt and Effective Treatment (B1)<br>Malaria in pregnancy (B1) | |
| Senegal (Round 1) | 5 of 14 indicators (<19%) | Under 5 treatment (19%) | Procurement delays |
| *Somalia (Round 2) | 10 of 24 indicators (0%-75%) | Uncomplicated cases treated ACT and non-ACT (250%)<br>Malaria in pregnancy (A) | |
| Sudan (N) (Round 2) | 7 of 10 indicators (0-68%) | Prompt and Effective Treatment (B2) | Procurement delays due to global shortage of commodities<br>Delays due to additional safeguard measures |
| *Sudan (S) (Round 2) | 2 of 16 indicators (0%)<br>5 of 16 indicators (<59%) | Prompt and Effective Treatment (A)<br>Malaria in pregnancy (B1 – 59%) | |
| Uganda (Round 2) | 15 of 22 indicators (<11%) | Prompt and Effective Treatment (0%) | Poor performance due to loss of momentum associated with suspension of Global Fund grant |
| Uganda (Round 4) | 9 of 11 indicators (0%) | Prompt and Effective Treatment (0%)<br>Under 5 home-based treatment (0%) | Delays in appointment of Third-Party Procurement Agent<br>Delays in procurement of ACTs |

* (blue) indicate stronger performance on Level-3 People reached indicators

Table 5: Review of Malaria grant Performance Indicators. Source: Global Fund 2007

All the 17 countries with poor performance also showed that they were unable to reach the most highly weighted level 3 treatment indicator. The performance reviews of countries which were earmarked for reprogramming clearly showed that countries faced global shortages of ACT commodities and procurement delays. At least 14 of the 17 countries (82%) experiencing underperformance had difficulties with ACT procurement. The review of Grant Performance Reports and Grant Score Cards showed that countries were also rated strictly on performance measures (i.e. contextual information was not given due consideration in the performance review process). For example, whilst the Nigeria Round 2 Grant Performance Report acknowledged procurement and supplier delivery delays, the LFA gave a rating of 'B2' and the FPM gave a 'C' rating stating as justification, "...obvious non-performance of the grant and major programme issues in accelerating service delivery prior to Phase 2."

## SECTION VIII. ANALYSIS AND RECOMMENDATIONS

Section VIII examines an analysis of the following topics: a) learning organisations; b) the effects of GHIs at global and country-levels; c) scaling up and intervention complexities, including rapid scale up and its effects on performance-based funding; d) the issue of policy options, choice and country ownership; e) making performance-based funding work for health and the Global Fund; f) diagonal financing; and g) key findings for the research and for policy and practice for the study.

### A. A Learning Organisation: What lessons for the Global Fund?

Nevis, Ghoreishi and Gould (1995) state that the focus of learning theorists such as Senge and Argyris and Schon is on the learning required to make transformational changes – changes in basic assumptions – that organisations need in today's fast-moving, often chaotic environment. It provides a more complete model for observing and developing organisational learning.[192] They stressed that learning organisations do not wait for problems to emerge; rather reflection becomes part of the way business is conducted. Through this process, they question the original assumptions and search for deep systems (e.g. Jensen's double-loop learning) and solutions to problems.[193] Similarly from an organisational theory perspective, Cook and Hunsaker noted that a key function of managing is to adapt or transform system elements to achieve goals within a dynamic environment.[194]

Calvert, Mobley and Marshall (1994) reinforced the notion that learning organisations are works in progress, both conceptually and practically. Learning organisations accept leanings from failure learning (what went wrong) and success learning (what went right). In a study of more than 150 new products of Copeland Corporation, a highly successor compressor manufacturer, they concluded that "the knowledge gained from failures is often instrumental in achieving subsequent successes" (i.e. failure is the ultimate success). To continuously improve, there is also a need to have a commitment to learning.

[192] Nevis, Ghoreishi and Gould, 1995, p.3
[193] Ibid., p. 16
[194] Cook and Hunsaker, 2001 p. 20

## B. The Effects of GHIs at Global and Country Levels

The influx of funds has been accompanied by major changes in the institutional landscape of global health, with the creation of several new Global Health Initiatives[195] and other innovative financing mechanisms bringing in substantial increase in financing including the Global Fund.[196] International health financing had substantially increased over the last decade from USD 5.6 billion in 1990 to USD 21.8 billion in 2007.[197] Since the Global Fund was established in 2002, it has approved a total of 123 grants to 73 malaria endemic countries.

According to Tangcharoensathien and Patcharanarumol (2009), GHIs claim to contribute to health systems strengthening is controversial and strong health systems are seen as a prerequisite for successful GHI implementation.[198] Biesma et al. (2009) also highlight the negative effects of GHIs which include distortion of recipient countries' national policies, notably through distracting governments from coordinated efforts to strengthen health systems and re-verticalisation of planning, management and monitoring and evaluation systems.[199]

At the global level, the rapid pace of the Global Fund's reprogramming efforts attributed to a global shortage of ACTs in 2004 and according to WHO informal consultation with ACT manufacturers, this in turn increased artemisinin prices and the market demand created expansion of artemisinin plantation and production. Despite external factors, the Global Fund and partners attempted to facilitate the necessary steps and actions required for transitioning of ACT. However, the actions were not sufficient to address the smooth transition of ACTs.

Whilst Biesma et al. (2009) describes the Global Fund's lack of country presence as a radically new financing mechanism in the international aid architecture,[200] Wilkinson et al. (2006) cautioned the lack of a country presence and the slowness of the Global

[195] A GHI is defined as 'a blueprint for financing, resourcing, coordinating and/or implementing disease control across at least several countries in more than one region of the world'.
[196] By May 2006, the Global Fund had contributed 64% of all international funding for malaria with approximately 50 percent of these funds to be used towards procurement of malaria commodities.
[197] Ravishankar et al. 2009, p. 2113
[198] Tangcharoensathien, V. and Patcharanarumol, W. 2009, p. 101
[199] Biesma, et al. 2009, p. 239
[200] Biesma, et al. 2009, p. 240

Fund and its global multilateral and bilateral partners to respond to the need for stronger technical support to countries, often delayed and impaired grant implementation.[201]

At times, GHIs create fragmentation, especially when countries have little capacity to negotiate and harmonise donor programmes.[202] The Global Fund Tracking Studies (2003-2004) and baseline SWEF studies (2004-2005) conducted by Brugha et al. (2004), Stillman and Bennett (2005) reviewed disbursement, absorption and management of GHI funds, indicating that countries reported immense pressure due to the Global Fund's performance-based disbursement conditions. The PBF approach was not seen as inherently wrong but as compounding problems of low absorptive capacity at country level due to weak country systems.[203] Some key issues for consideration include the wider challenges of implementing performance-based funding whilst utilising health finances effectively, for strengthening of health systems, in order to achieve MDGs.[204]

**Lack of Evidence for GHIs**

WHO's Maximising positive synergies collaboration group (2009) pointed out that rigorous research and evidence of GHI on country health systems remain insufficient due to the relatively short timeframe of the launch of large GHIs (i.e. less than 10 years), arrangements for assessments was not established and more importantly, the scientific community has been slow to develop research methods that help in the elucidation of the complex nature of the interactions between GHIs and health systems.[205]

Similarly, Schaferhoff, Campe and Kaan (2009) stated that the research community should keep an eye on the complex performance of Private-Public Partnerships (PPPs),[206] as the rise of PPPs has led to a more fragmented and uncoordinated global arena. PPPs are intended to supplement rather than replace traditional intergovernmental organisations, and although some of them have proven to be effective

[201] Wilkinson et al. 2006, p. 246
[202] Tangcharoensathien, V. and Patcharanarumol, W. 2009, p. 103
[203] Ibid., p. 246
[204] Low-Beer et al, 2007, p. 1308
[205] WHO Maximising positive synergies collaboration group, 2009, p. 2139
[206] For the purposes of this paper, PPPs and GHIs are used interchangeably.

governance instruments, PPPs may have unintended side effects that could distort interstate policies.[207]

### C. Scaling up and Intervention Complexities

The term, scaling up is used primarily to describe the ambition or process of expanding the coverage of health interventions, but can also refer to increasing the financial, human and capital resources required to expand coverage.[208] Mangham and Hanson (2010) point out that a substantial inflow of external resources can adversely impact on government capacity for management, planning, budgeting and service delivery. This could include constraints and barriers at: 1) community and household level; 2) health service delivery; 3) health sector policy and strategic management; 4) cross-cutting public policies; and 5) environmental and contextual characteristics.[209] The ability to scale up health service delivery can be affected by a number of factors including a lack of infrastructure and equipment, inadequate drugs and medical supplies, shortage and distribution of qualified staff, weak management, technical knowledge and inadequate supervision.[210] They further noted that some constraints can be eased with additional funding, though it can be more difficult to overcome systemic issues.[211]

Intervention complexities for ACT reprogramming could also be attributed to a number of factors including: weak or lack of communication/coordination; short grant life span; reluctance of countries to change national drug policy; ACT implementation which were already in progress; limitation of grant size; problems with performance-based funding framework; implementation challenges including procurement delays; and, misclassification or site-specific implementation.

Although the initial ACT production and procurement issues have been largely resolved, implementation continues to be a challenge at country-level. The delays related to effective coordination at the global partnership level and in providing required technical guidance and coordination resulted in implementation delays at country-level. The lack of proper procurement planning further hindered implementation and directly affected performance of Global Fund malaria grants. Countries in turn could not show the

[207] Schaferhoff, Campe and Kaan, 2009, p. 465
[208] Mangham & Hanson, 2010, p. 85
[209] Hanson et al. 2003, p. 6
[210] Ibid., p. 6
[211] Mangham & Hanson, 2010, p. 88

essential results to secure additional funding in subsequent rounds, which were required for scaling up of ACT implementation efforts.

The Global Fund initiated the ACT transition process, which on one hand, acted as a catalyst for global level coordination efforts along with RBM partners. On the other hand, external forces and other constraining factors such as limited pre-qualified suppliers, production needs, lack of producer confidence in forecasting and quantification efforts to guarantee orders, and reluctance of countries to switch to ACTs led to difficulties in planning to adequately address global shortages of ACTs.

**Intervention Complexities**

Partnerships between public and private sectors have also changed the health policy environment.[212] Walt, G. et al. (2008) highlight that the policy environment has become increasingly complex, with policies influenced by global decisions as well as by domestic actions.[213]

Several factors significantly impacted ACT reprogramming at various levels including at the Global level, within the Global Fund Secretariat and at the country level. Each of these levels was a contributing factor in the success of ACT reprogramming and the dynamics between these levels further complicated the understanding and implementation of ACTs in the reprogramming process.

Beyond the drug efficacy issues, the countries' use of ACTs is dependent on a number of factors including drug cost, accessibility and availability at local and end user levels, government policies, informal and private sector engagement, and public information. Other factors include: monitoring adverse effects; safe practices for high-risk groups such as pregnant women and children; availability of paediatric formula for infants; quality assurance; and, other broader health systems requirements. Proper procurement planning was a key factor. All these factors should have been guided by evidence of effectiveness at community level and implemented within a national context when drug policy change was being considered.

[212] Walt, G. et al., 2008, p. 309
[213] Ibid., 2008, p. 309

## D. Rapid scale up and its effects on performance-based funding

Morrissey (2004) draws on the example of trade policy reforms in Sub-Saharan Africa to point out that reform is a relatively slow process and that conditional lending per se is not an effective instrument for ensuing relatively rapid policy reform. In cases where reform was implemented quickly and rapidly (i.e. **the big bang approach**), the cases ended up to be almost all failures.[214] Aid plays an important role in policy not by dictating choice but by informing and supporting the policy environment.

The **rapid reprogramming** for the switch to ACTs and implementation efforts (i.e. Morrissey's big bang approach), which took place due to significant funding from the Global Fund and international pressure highlighted challenges faced by the countries requested to reprogramme. The rapid change process showed the lack of anticipation and inadequate planning for the transition process. The key challenges reflect the sheer complexity of changing policies as well as building a consensus around the evidence amongst many partners and stakeholders at global and country levels, as voiced during the initial process at the Nairobi meeting and subsequent global coordination effort.

In order to address ACT transition for countries identified during the malaria review process, the Global Fund spearheaded major reprogramming efforts focusing on the **rapid creation of special instruments** (e.g. pooled financing in the form of a memorandum account, accelerated Phase 2 funding etc.).

The creation of the Memorandum Account was in itself insufficient for many of the private manufacturers. Manufacturers wanted the Global Fund to act as a guarantor for the procurement commitments made by countries and the Global Fund was not in a position to assume legal responsibility or bear the associated risk related to procurement on behalf of countries. The gap between private and public sector expectations as well as the reluctance of many countries to act on the switch to ACTs meant that the set-up of the ACT Memorandum Account became in the end, an ineffective instrument.

The Global Fund Board meeting in June 2004 approved USD 90 million (i.e. an accelerated approval of a portion of Phase 2 funding) to accommodate the transition costs associated with the switch to ACTs and reprogramming of malaria grants. Due to

[214] Ibid., p. 164

a number of factors (e.g. timeline, funding requirements etc.), Nigeria was the only country which availed itself to access the funds from the allocation of USD 90 million. Acceleration of Phase 2 funds as a new flexible instrument was in retrospect, an ineffective instrument for many countries earmarked for ACT reprogramming.

Research findings show that from a total of 22 countries which were requested to reprogramme in 2004, only 4 countries made a decision to switch to ACTs; namely, Nigeria, Angola, Gambia and Somalia. Follow-up on the countries requested to transition to ACTs showed that many countries in fact, did not transition to ACTs at the pace expected by the Global Fund. This could be attributed to a number of factors including: weak or lack of communication and coordination; short grant life span; reluctance of countries to change national drug policy; ACT implementation which were already in progress; limitation of grant size; problems with performance-based funding framework; implementation challenges including procurement delays; and, misclassification/site-specific implementation.

The Global Fund's Partners for Impact Report (2007) acknowledged that malaria grants were slow in their first phase of implementation due to procurement and global supply issues for ACT treatment as well as for long lasting insecticide treated nets. The lack of programmatic progress and achievement for malaria during Phase 1 (2004-2006) were evident by the fact that an improvement in results of performance-based funding were gradually witnessed only in 2006 with an increase from 60% to 73-77% after Phase 2 evaluation.[215]

Subsequently, the success rate for malaria grants was cited as being the lowest for Global Fund Round 5 and Round 6. One of the main reasons cited was a global supply shortage of commodities including ACTs, and as a result many countries were not able to show a number of important treatment coverage indicators. There were 22 out of the 28 countries which applied to Round 5; of which 4 countries (14%) were successful in their proposal application to the Global Fund.[216] Seventeen of the proposals were marked Category 3 (not recommended for funding/encouraged to resubmit) and one was marked Category 4 (not recommended for funding). Similarly, for Round 6, of the 24 countries which applied, 6 countries (25%) were successful in securing Round 6

[215] The Global Fund. Partners in Impact, 2007. p. 47
[216] One country (Guinea) succeeded through an internal appeals process where the TRP reversed their decision.

funding. Sixteen countries received Category 3 and 2 countries received Category 4 ratings.[217]

The majority of Global Fund grants which were earmarked for reprogramming suffered from reaching planned targets. A review of available Global Fund Grant Performance Reports and Grant Score Cards for the 26 countries[218], 17 of the 26 countries (65%) showed poor performance indicators. All the 17 countries with poor performance also showed that they were unable to reach the most highly weighed level 3 treatment indicator. The performance reviews of countries with malaria grants which were earmarked for reprogramming clearly showed that countries faced global shortages of ACT commodities and procurement delays. At least 14 of the 17 countries (82%) experiencing underperformance had difficulties with ACT procurement. In summary, for both Rounds 5 and 6, there was an 80% failure rate for all the malaria proposals submitted by the countries earmarked for reprogramming and therefore, were not able to secure additional funding.

Low-Beer et al. (2007) cited that PBF provides clear incentives to achieve results and has been used by organisations such as Global Fund. Performance-based funding is an important instrument and can act as a catalyst; however, in the case of malaria reprogramming and the **rapid switch to ACTs**, creation of special instruments alone regardless of its innovation and flexibility did not necessarily facilitate the change or desired outcomes at country level.

### E. Policy Options, Choice and Country Ownership

Morrissey's paper (2004) states that willingness of government to implement reforms (i.e. to alter policy choices) much depends on beliefs regarding the effect of given policies and policy options.[219] The central issue is therefore **choice** and **not solely ownership**. He stressed that rather than impose conditions, donors should provide information and advice and encourage the countries to make **policy choices**.[220]

Malaria treatment policy should be part of a comprehensive strategy in addressing the overall health system and the impact of other policies on the health sector. However,

[217] Angola's proposal was screened out for CCM non-compliance and was not submitted to the TRP for review.
[218] Chad and Malawi were excluded from the review. Chad did not reprogramme and Malawi had no progress indicators.
[219] Ibid., p. 166
[220] Ibid., p. 167

more systemic issues such as PR capacity at country level, and the larger absorptive capacity concerns became more of a challenge for the Global Fund. These issues cannot be addressed alone without due attention to constraints of the health system or the involvement of partners.

The switch to ACTs highlighted challenges faced by all countries which underwent the transition process and evidenced by the lack of anticipation and proper planning for the transition process. The key challenges reflect the sheer complexity of changing policy as well as building a consensus around the evidence amongst global and in-country partners.

## F. Making PBF work for Health and the Global Fund

Eisenhardt, K. (1989) stressed that incentives motivate an agency or an organisation to change how it operates. These changes can affect any element of the agency's structure or administration, although major changes may require bigger incentives. The most direct approach is for rewards to agencies to be based on their achievement of predetermined output or outcome targets. Incentives may include: personnel related incentives; (personnel recognition, promotion, group awards and recognition, and bonuses) or program related incentives; (standardized performance information, subsidy or taxation, or introduction of market schemes (e.g. competitive sourcing or outsourcing).[221] Multiple incentives must be attached to multiple performance measures.

Evidence based policy and performance measurement studies conducted by Kasdin (2010) stated that performance measures are not an end in themselves but have their limitations. They are a necessary but are not a sufficient condition for good management where appropriate incentives are required. In general, uncertainty in measuring an agent's performance reduces the quality of the contract between principal and agent, and accountability deteriorates.[222]

Scholars (Buse and Waxman, 2001) acknowledge the limits of the vertical approach adopted by public-private partnerships might create "islands of excellence in seas of

[221] Ibid., p. 62
[222] Eisenhardt, K., 1989 p., 57-74

under provisions".[223] Low-Beer et al. (2007) also caution that PBF may penalise poorer countries, and may not be flexible enough to contribute to health systems generally.

Performance was also affected for the majority of Global Fund grants which were earmarked for reprogramming suffered from reaching planned targets. According to a review of available Global Fund Grant Performance Reports and Grant Score Cards for the 26 countries,[224] 17 of the 26 countries (65%) showed poor performance indicators.

As previously indicated, the performance reviews of countries which were earmarked for reprogramming clearly showed that countries faced global shortages of ACT commodities and procurement delays. At least 14 of the 17 countries (82%) experiencing underperformance had difficulties with ACT procurement.

## G. A marriage made? Diagonal approach to Global Health Financing

Ooms et al. (2008) highlighted that a solution to the potential polarisation between 'vertical' and 'horizontal' financing of health services in developing countries has been proposed by Julio Frenk and Jaime Sepulveda, as the 'diagonal' approach, defined as a "strategy in which we use explicit intervention priorities to drive the required improvements into the health system, dealing with such generic issues as human resource development, financing, facility planning, drug supply, rational prescription, and quality assurance.[225] Diagonal financing would help finance the required disease-specific AIDS, Tuberculosis and Malaria programming, and would help fund increased programme integration and coordination, and contribute to strengthening underlying health systems.[226]

Schaferhoff, Campe and Kaan (2009) point out that service delivery issues are dependent on the capacity of the prevailing health systems. Initiatives such as the Global Fund and PMI, PEPFAR are seen as vertical programmes discouraging an integrated approach to scaling up health service delivery. More recent thinking emphasises the potential gains from using health systems (also referred to as the diagonal approach) to

[223] Buse and Waxman, 2001, p. 2
[224] Chad and Malawi were excluded from the review. Chad did not reprogramme and Malawi had no progress indicators.
[225] Ooms et. al. 2008, p. 2
[226] Ibid., p. 5

address the generic problems of human resource development, financing, planning, drug supply and use and quality assurance.[227]

Low-Beer et al. (2007) states that there are many challenges to successful PBF including how to ensure flexible "diagonal" funding so that "vertical" disease-specific initiatives on AIDS, Tuberculosis and Malaria can also support general health systems.[228] He added that "Diagonal Financing" can support health systems – at its best, PBF combines the inventiveness of country solutions with the sharp focus and incentives of performance, ensuring people receive services with urgency. The Global Fund provides "diagonal financing" with an emphasis on achieving disease goals while allowing finance to more broadly strengthen the supporting health sector.[229]

However, Low-Beer et al. stressed that there is inherent risk in the results – the variability in returns in health programmes (well performing programmes return twice the results) is not always recognised and needs to be actively managed with financial incentives and technical support. He notes that many programmes do not use Global Fund finance as flexibly and effectively, and the need to "mind the gap" financially in health systems.[230]

Research conducted by Centre for Global Development (CGD) to identify large scale health programmes that have had a substantial impact on mortality and morbidity (Levine et al. 2004) examined 17 case studies that satisfy their criteria of cost-effective health interventions which has demonstrated a clear and measurable impact. They acknowledged that some of the best-known examples are vertical programmes, which are centrally managed, disease-specific initiatives that are isolated from broader health services. In several of the success stories, the boundary between a vertical approach and efforts to strengthen health systems is broken down, showing how disease-specific efforts can work with and strengthen routine health service delivery.[231]

### H. Systems Wide Effect: ACT Transition and Implementation Issues

The TERG assessment report of Global Fund Proposal Development and Review Process, noted concerns that the Global Fund system of "rounds" is geared to support

[227] Mangham & Hanson, 2010, p. 89
[228] Low-Beer et al. 2007, p. 1308
[229] Ibid., p. 1310
[230] Ibid., p. 1310-1311
[231] Levine, R., et al. 2004, p. 5

discrete projects rather than strategic programmes is undermining coordinated approaches such as SWAPs for health and development, and is a major source of disharmony for national planning, implementation monitoring and reporting systems. It was noted that there were persistent high transaction costs associated with receiving Global Fund support, including reallocation of human resources from other programmes.

It was widely recognised that changes in malaria treatment policy were complex which takes considerable time at country-level. In addition to policy change, a transition period is often required, (e.g. Ghana) before full implementation can be carried out.

The **Ghana** example clearly shows that technical considerations for implementation such as ACTs involves drug policy and regulatory issues (e.g. drug registration and usage of new drugs, drug enforcement including phasing out old drugs, elimination of monotherapies, monitoring of counterfeit drugs), quality assurance, as well as the establishment of national guidelines, supply chain management (e.g. inventory control, drug monitoring and distribution), advocacy and information dissemination of national treatment guidelines, inventory control, monitoring of existing drugs and adverse drug reactions).[232]

Adverse effects and interaction with the private sector were seen in the case of Indonesia. According to a study conducted by the Ministry of Health of **Indonesia** in 2004-2005, patients were experiencing side effects from their use of the first line drug of Artesunate+Amodiaquine. As a result, the national programme manager reported low compliance. Patients started using piperaquine-dihygroartemisinin, the latest ACT produced in China and Vietnam was widely available in the informal sector at an affordable price (market price of USD 1.50/treatment). However, this drug had not been approved by WHO and monitoring was difficult.

System-wide effects were clearly seen in **Malawi**, where the Global Fund had difficulty implementing its performance-based funding approach within a SWAps environment.[233] As a result, Malawi was unable to show any progress on performance of their Round 2 grant.

[232] Excerpts from RPM Plus Presentation: Global Fund West and Central Africa Regional Malaria Workshop, Dakar, Senegal, March 2006.
[233] SWAp is a form of Programme Based Approach (PBA) applied at the sector level.

**At the Global Level:** Global Fund reprogramming efforts attributed to a global shortage of ACTs in 2004 and according to WHO informal consultation with ACT manufacturers, this in turn increased artemisinin prices and the market demand created expansion of artemisinin plantation and production.[234] In addition, the mismatch between increased demand for ACTs in the public sector mainly due to the low approval rates of Rounds 5 and 6 and delayed disbursements and utilisation of Round 4 funds, created major reductions in artemisinin prices. There was also a ripple effect from concerns over farmers reacting to decreased demand resulting in the risk of ACT shortages in 2008-2009.

## I. Recommendations

The Global Fund and partners attempted to facilitate the necessary steps and actions required for transitioning of ACT against numerous external factors. However, the actions were not adequate to address the smooth transition of ACTs. The following recommendations reflect additional measures for consideration when transitioning to ACT or other treatment, based on new scientific evidence.

**Recommendation 1: the need for early Partnership Coordination**

Country presentations at the Nairobi Meeting (Sudan, Pakistan, Niger, Benin, Uganda, Nigeria, Ghana, Kenya and DRC) clearly highlighted the challenges faced by many countries, reflecting the sheer complexity of changing policy as well as building consensus among all stakeholders on the need to change policy.

Further analyses are required to take into consideration the cost benefit of regime change and to ensure long-term availability of financing ACTs and supply. Procurement challenge will require building consensus with in-country implementers, taking into consideration the question of registration, drug formulations (especially for paediatrics and pregnant women), monitoring adverse reactions, private sector engagement. Partners will also need to ensure that the path is laid out for immediate and future technical assistance requirements for countries.

[234] WHO informal consultation with manufacturers of artemisinin-based pharmaceutical products, August, 2007, p. iii.

**Recommendation 2: TRP Review Process**

TRP briefing by RBM Secretariat (as planned from Round 7 onwards) prior to proposal review process would have been helpful to the reviewers including orientation for new TRP reviewers. Round 4 malaria success rate was in part due to early TRP involvement in the malaria country review process. However, there was less involvement of the TRP in the ongoing ACT implementation process of countries and the effects of ACT implementation delays appear to have influenced TRP decision for subsequent rounds.

**Recommendation 3: Sufficient Time for Planning and Coordination**

As indicated for Ghana, planning and coordination particularly for the transition period include identification of stakeholders, formation of a transition committee and related working groups to take into consideration development of a drug policy, programme planning, development of an implementation plan and monitoring and evaluation requirements. A change to new drug policy would also take into consideration assessments for existing treatments as well exploring alternative drugs, resource consideration including cost to patients and the to the overall health sector, and compilation of evidence for resistance.

Global Fund's funding decisions for changing treatment guidelines should be based on proper planning and coordination. Accordingly, the Global Fund Secretariat should provide sufficient time for planning and coordination to take place, rather than rushing to make funding decisions, which would ultimately affect beneficiaries and performance targets at country-level.

**Recommendation 4: Procurement Coordination**

Procurement activities including pharmacovigilance, drug efficacy, quality assurance, and Monitoring & Evaluation (M&E) should be reflected in future country workplans. Large scale implementation should include national budget as well as complimenting identified gaps with the involvement of wider partnerships. One of the weaknesses for the Round 6 proposal review process indicated that the proposals did not contain clear gap analysis and PSM plans were inadequate. The necessary production lead time should be given due consideration, as well as time required for country processes including procurement planning.

**Recommendation 5: Improve Communication at all Levels**

Continuous feedback and communication is required with all partners, i.e. between Global Fund Secretariat and countries to account for ACT implementation issues at country-level. Strong and sustained advocacy is required amongst all stakeholders to facilitate and address global and donor pressures as well as in-country stakeholder consensus on implication of national treatment policy changes. Important communication issues including dissemination of guidelines to health care providers and pre- and post-in-service training, including IEC and BCC strategies should have high priority.

**Recommendation 6: The Global Fund Secretariat Coordination**

The Global Fund Secretariat should appoint and maintain a focal point for technical and operational coordination efforts to maintain and strengthen linkages within the Secretariat (e.g. between operations, policy, strategy and procurement) as well as with external partners for continuity and coordination of reprogramming efforts.

**Recommendation 7: Conduct Orientation Courses**

Although there was an orientation session provided to the FPMs as part of the ACT reprogramming plan, due to the lack of a technical focal point and a high turnover of FPMs, the new FPMs were not fully aware of the implications of ACT reprogramming when communicating with countries. For every significant reprogramming effort (such as the transition to ACTs), sustained induction and orientation courses should be provided to new Fund Portfolio Managers in order to facilitate improved coordination effort at country-level.

**Recommendation 8: Considerations for Country Ownership**

Considerations for countries' decisions must remain paramount if the Global Fund is to maintain its core principles of country ownership. Operational and implementation challenges related to the roll out of ACTs were voiced as early as September 2004 at the Nairobi meeting. Yet, efforts to address these concerns within the constraints of external pressure and framework were insufficient for effective ACT reprogramming.

**Recommendation 9: Consideration for Performance-based Funding during Phase 2 Review Process**

Although the Global Fund Secretariat took into consideration contextual information as part of the Phase 2 review process, the Global Fund still held countries accountable for low or non-achievement of planned level 3 core indicators (i.e. people reached indicators). Despite the fact that this was directly attributable to external factors, emphasis should be given to contextual information and weightings should be adjusted to reflect performance-based indicators, particularly in cases of significant reprogramming.

**Recommendation 10: Consideration for Performance-based Funding during new grants**

Creation of new instruments should not be developed in isolation but within the in-country operational framework, with realistic timelines, and recognition for on the ground situation at country level.

**Recommendation 11: Continued Support for New Research and Development (R&D)**

Continued support for R&D (e.g. especially efforts spearheaded by MMV) is required in light of the market inadequacies for ACTs and before widespread resistance to ACTs take effect. It is estimated that on average it takes approximately 10 years for a potential new drug to move from discovery to pre-clinical and clinical development and is anticipated that a synthetic ACT will become available within this time.[235] Other ACTs are underdevelopment including chlorproguanil-dapsone (Lapdap) with artesunate by GlaxoSmithKline under the sponsorship of MMV and a fixed-ratio drug combination of piperaquine-dihydroartemisin is being developed to treat uncomplicated malaria.[236]

Key Findings for research from the Study:

- Sufficient attention needs to be given to intervention complexities and unintended side effects and fragmentation as a result of GHIs especially within the context of implementation of vertical programmes.

[235] KIT Royal Tropical Institute, 2006. pp. 18, 51
[236] KIT Royal Tropical Institute, 2006. p. 16

- Application of a one size fits all performance-based measurement schemes within the context of rapid policy change can penalise countries trying to achieve results.
- Synergistic nature and approach to vertical and horizontal financing including diagonal approach to financing could be considered as alternative approaches.
- A big bang approach (i.e. implementation quickly and rapidly) has system-wide effects at country level.

Key Findings for policy and practice from the study:

- There is a need for closer and continued partnership coordination for consensus building, and to meet immediate and future technical assistance requirements.
- TRP Briefing is essential for future review process including orientation for new TRP members.
- Sufficient lead time is required for planning and coordination. The Global Fund funding decisions for changing treatment guidelines should be based on proper planning and coordination including procurement coordination. The necessary production lead time should be given due consideration, as well as time required for country processes including procurement planning.
- Improvement in communication at all levels (i.e. Global, Global Fund Secretariat and Country levels) as well as continuous feedback and communication are required with all partners, i.e. between Global Fund Secretariat and countries to account for ACT implementation issues at country-level.
- Ensure and maintain focal points for technical and operational coordination efforts to maintain and strengthen linkages within the Secretariat (e.g. between operations, policy, strategy and procurement) as well as with external partners.
- Strong and sustained advocacy is required amongst all stakeholders to facilitate and address global and donor pressures as well as in-country stakeholder consensus on implication of national treatment policy changes.
- For every significant reprogramming effort (such as the transition to ACTs), induction and orientation courses should be provided on a regular basis to new Fund Portfolio Managers in order to facilitate improved coordination effort at country-level.
- Ensure policy choices and country ownership to maintain its core principles of country ownership.

- Special considerations should be provided for Performance-based Funding within significant reprogramming context for Phase 2 renewal of grants as well as for new rounds of applications. Although the Global Fund Secretariat took into consideration contextual information as part of the Phase 2 review process, the Global Fund still held countries accountable for low or non-achievement of planned core indicators (i.e. level 3 on people reached indicators) even though this was directly attributable to external factors. Emphasis should be given to contextual information and weightings should be adjusted to reflect performance-based indicators.

# SECTION IX. CONCLUSION

## A. An Organisational Analysis of the Global Fund

The paper examined organisational and policy analysis of the Global Fund at its inception and documented processes of change (e.g. organisational and operational framework, proposal approval processes etc.) in the Global Fund in a rapidly growing institution. The Global Fund case study is then analysed from the perspective of Peter Senge's notion of the learning organisation, and the proposition that when organisations are in situations of rapid growth and change, only those that are flexible, adaptive and productive will excel and achieve its mission and objectives. Peter Senge's five disciplines of the learning organisation (systems thinking, personal mastery, mental models, building a shared vision and team learning) are applied to an organisational analysis of the Global Fund at three levels: at the Global Fund Board level (e.g. Board policy changes); Secretariat level (e.g. organisational and structural changes); and, at country level (e.g. changes to proposal guideline process, grant signing process, Principle Recipient arrangements, the fiduciary and programmatic management process of the Local Fund Agent).

The objectives were: 1) to gain a better understanding and insight into challenges and constraints of the Global Fund by examining the organisational structure and mechanisms related to performance-based funding approach; 2) to review and analyse key achievements of performance-based funding to date; and 3) make appropriate recommendations to improve effectiveness of significant reprogramming within the performance-based funding approach for the Global Fund using reprogramming of ACT as an example.

## B. Performance-Based Funding

The paper examines the organisational framework from 2002 to 2007 with a specific focus on performance-based funding tools including elements of reprogramming as a PBF instrument and implications of significant reprogramming for the Global Fund. The assessment takes a close look at the implications of significant reprogramming through a case study of a more effective but higher cost transition to Artemisinin-based Combination Therapy in 30 of the Global Fund malaria grants based on a review of a

total of 44 grants with an anti-malarial component. The paper highlights the process and subsequent outcomes of reprogramming of 30 country grants transitioning or not using ACTs at that time.[237] A number of innovative methods were developed to realise key PBF objectives. The next section reviews the finding regarding these special instruments.

### C. Creation of Special Instruments

As a follow-up to the review process, the Global Fund spearheaded major reprogramming efforts focusing on the rapid creation of special instruments (e.g. creating of a memorandum account, accelerated Phase 2 funding etc.) in order to address ACT transition for countries identified during the malaria review process.

The findings of this study show that although the country recipients were provided with the necessary tools required for the transition (i.e. funding and the provision of flexible reprogramming tools), they were not sufficient for effective transition as the unintended effects stemming from significant reprogramming became evident. The creation of the Memorandum Account was in itself inadequate for many of the private manufacturers. The gap between private and public sector expectations as well as the reluctance of many countries to act on the switch to ACTs meant that the set-up of the ACT Memorandum Account became in the end, an ineffective instrument. Similarly, acceleration of Phase 2 funds as a new flexible instrument was ineffective as Nigeria was the only country which availed itself to access funds from the allocation of USD 90 million.

Follow-up on the countries requested to reprogramme and transition to ACTs also showed that many countries in fact, did not transition to ACTs at the pace expected by the Global Fund; only 4 countries made a decision to switch to ACTs; namely, Nigeria, Angola, Gambia and Somalia. ACT reprogramming efforts, (e.g. global supply shortage of commodities, limited supplier selection), directly affected the success of future rounds of malaria grants (e.g. for both Rounds 5 and 6), resulting in an 80% failure rate for all the malaria proposals submitted by the countries earmarked for reprogramming.

[237] The review excluded 11 grants already requesting ACTs, and 3 grants which do not need a transition to ACT.

## D. Global Health Initiatives on Country Health Systems

The increase in overall resources for international health has also changed the global health landscape in terms of additional resource flows to the countries and subsequent pressure on capacity of countries to respond. An analysis of the method through which resources on this scale are managed and delivered is therefore of considerable importance.

The paper examined policy decision-making process at multiple levels, analysing efforts to accommodate changing scientific evidence at a global scale and the requirements on country level policymakers to change national drug treatment policy. Centred on an assessment of 30 country grants relating to drug efficacy reviews, the analysis relates the performance of those reprogramming grants to the criteria laid out in Global Fund Grant Performance Reports as well as assessing the consequences for securing funds in future rounds of applications. The findings also illustrate the realities of external factors associated with global partnership and interagency collaboration, country-readiness, global demand and supply side issues.

The dissertation provides particular insights into unintended effects of GHI and intervention complexities in malaria programmes within the health sector. This covers both supply side (e.g. effects on ACT producer behavior, barriers to entry) and demand side of ACT reprogramming (e.g. country perception, concerns expressed for policy change and sustainability of financing). The Global Fund reprogramming efforts attributed to a global shortage of ACTs in 2004 which in turn increased artemisinin prices, as well as expansion of artemisinin plantation and production. ACT shortages in turn affected programme performance of malaria grants and in securing additional funding for subsequent rounds (e.g. Round 5 and Round 6).

The paper examines some of the elements of scaling up as defined by Hanson et al. (2003) in terms of issues related to: 1) health service delivery and in particular, procurement, quantification and supply chain management issues; 2) health sector policy and strategic management formulation (i.e. policy options for informed decision making process); 3) cross-cutting public policies and understanding intervention complexity; and, 4) understanding environmental and contextual characteristics. It also addresses scaling up for international funding, and issues regarding the importance of country ownership.

As a learning organisation, the Global Fund will need to continue to leverage on creative innovative mechanism for malaria (as in the case of ACT reprogramming) and other new treatments. This research has shown that the creation of special performance-based instruments alone was not sufficient for the successful utilisation of the performance-based funding approach. If failure can be considered the ultimate success as cited by Calvert, Mobley and Marshall (1994), then the Global Fund can commit to learning and to continuous improvement. As such, there is a need to be more focused, and reflective in the approaches taken by the Global Fund in order to address and put into place more systemic planning following the systems thinking approach of Peter Senge and other learning organisations, taking into account the interrelated processes which have repercussions on other variables in the system (e.g. shifting drug treatment policy entail appropriate changes, not only within the operational processes but also intervention within the health system as a whole).

This notion is reinforced by Biesma et al. (2009) in a review of GHI's on country health systems, studies conducted across 2002-2007 suggest that the Global Fund was beginning to adapt its early approach to fit with countries' priorities for aligning new funds with country systems.[238] The findings of Bisema's review of GHIs suggest that initially GHIs often had negative effects, and later as they learned lessons more often positive effects on health systems.[239]

Brugha et al. (2004) cited that rapid learning and applying lessons to get country-level processes right are essential to achieving the goal of the Global Fund. Brugha points out that the dilemma for the Global Fund has been **how to balance** the urgent need to control the three diseases against the time needed for countries to learn how to manage a new financing mechanism.[240] Tangcharoensathien and Patcharanarumol (2009) also called for **greater balance** from GHIs including ongoing health systems strengthening support, which is seen as positive developments towards maximising the effectiveness and sustainability of GHI investments.[241]

As the change and transition to ACTs have shown, innovation and creation of flexible instruments by the Global Fund even within the context of normal operational framework such as reprogramming, required **a balance**; a balance between the desire

[238] Ibid., p. 242
[239] Ibid., p. 248
[240] Brugha et al, 2004, p.99
[241] Tangcharoensathien, V. and Patcharanarumol, W. 2009, p. 103

to continually innovate before policies take into effect and repercussions of a system-wide effect in implementing Global Fund procedures at country-level. In addition, taking lessons from the change in malaria treatment policies, the Global Fund working together with partners and the broader community will need to provide countries with policy options to make appropriate policy choices (i.e. Morrissey's conditionality and aid effectiveness) and ownership at country level.

**Going forward**

Antimalaria drug policy change cannot be seen as a one-off process and therefore, further ongoing analyses are required in order to weigh in the cost benefits of change and ensuring long term availability and financing of ACTs.

Although the paper examined policy choices and effects at country-level, it does not address in detail constraints to scaling up or absorptive capacity at country level (e.g. human resource, infrastructure, management constraints) or the effects on community and household levels. Assessment of equity, health status and quality of life were not utilised as part of the thesis. As Mangham and Hanson (2010) highlights, "understanding intervention complexity can help in identifying strategies and highlight the importance of tailoring the approach to the specific intervention and country context to address the implementation constraints and new modes of operations".[242]

Furthermore, the opportunities created by the GHIs have yet to be fully exploited or utilised. As Feachem and Sabot (2007) noted, "It is recognised that the Global Fund as one of the major GHIs, is a massive experiment, embodying a number of theories about health and development finance (e.g. country ownership and achievement of results) which, at the time of inception, had yet to be tested on a large scale".[243]

Whilst there is limited evidence on approaches to and impact of scaling up, further research on unintended side effects of GHIs, diagonal approach to financing, intervention complexities, would be useful insights for the development of global health strategies and policies towards scaling up activities including as a result of new scientific evidence in the health sector.

[242] Mangham, L. and Hanson, K., 2010, p. 90
[243] Feachem, R., Sabot, O., 2007, p. 333

## Annex 1

| Country Mapping based on Readiness | | | | |
|---|---|---|---|---|
| | | GF Grant related readiness (e.g. grant signed, disbursement rate, PSM plan ready, PSM assessment done, costing done, tender process) | | |
| | | Early Stage | In Process | Mostly Completed |
| ACT implementation readiness (will they implement in 04, 05, or later) | Early Stage | Madagascar | Rwanda; Malawi | Mauritania; Burkina Faso |
| | In Process (Implementing in 2005) | | Uganda; Niger; DRC; Kenya; Ghana R4; Comoros; Nigeria R4; Sudan, South;Guinea Bissau;Somalia | Nigeria R2; Benin R1; Benin R3 |
| | Mostly Completed (implementing in 2004) | | Ethiopia | Sudan, North |

**Annex 2**

| **A: 11 countries already using ACT as first-line treatment** | | |
|---|---|---|
| Burundi | Liberia | Vietnam |
| Cambodia | Myanmar | Zambia |
| Guyana | Papua New Guinea | Zanzibar (Tanzania) |
| Lao PDR | Philippines | |

| **B: 8 countries in transition to use ACT as first-line treatment** | | |
|---|---|---|
| Benin | Ghana | Sudan (Northern) |
| Cameroun | Indonesia | Sudan (Southern) |
| Comoros | Kenya | |

| **C: 3 countries with *P. vivax* predominantly** | | |
|---|---|---|
| Georgia | Nicaragua | DPR Korea |

| **D: 22 countries not using ACT as first-line treatment** | | |
|---|---|---|
| Angola | Haiti | Pakistan |
| Burkina Faso | Madagascar | Rwanda |
| Chad | Malawi | Senegal |
| DR Congo | Mauritania | Somalia |
| Eritrea | Mozambique | Swaziland |
| Ethiopia | Nepal | Uganda |
| The Gambia | Niger | |

**Annex 3**

| COUNTRY | RECOMMENDATIONS FROM MALARIA GRANT REVIEW MEETING |
|---|---|
| Angola | Due to high failure rates with chloroquine and with sulfadoxine-pyrimethamine, these two drugs should not be used as monotherapy. Angola is recommended to change to ACT as 1st line treatment. Efficacy data on amodiaquine monotherapy furthermore suggest that this drug may not be an ideal partner-drug in artemisinin-based combinations. |
| Burkina Faso | High failure rates with chloroquine and low-to-moderate failure rates with sulfadoxine-pyrimethamine. These two drugs should not be used as monotherapy. Burkina Faso is recommended to change to ACT as 1st line treatment. Efficacy data on amodiaquine monotherapy suggest that this drug may be useful as a partner-drug in artemisinin-based combinations; however, complementary data on amodiaquine efficacy are needed. |
| Chad | High failure rates with chloroquine and with sulfadoxine-pyrimethamine. The two drugs should not be used as monotherapy. Chad is recommended to change to ACT as 1st line treatment. More efficacy data on amodiaquine are required to know, whether this drug will be appropriate as partner-drug in artemisinin-based combinations. |
| DR Congo | High failure rates with chloroquine and with sulfadoxine-pyrimethamine. The two drugs should not be used as monotherapy. DR Congo is recommended to change to ACT as 1st line treatment. More efficacy data on amodiaquine are required to know, whether this drug will be appropriate as partner-drug in artemisinin-based combinations. |
| Eritrea | High failure rates with chloroquine, and so it should not be used as monotherapy, except for the treatment of *P. vivax*. Relatively low failures rates observed with sulfadoxine-pyrimethamine; however, this drug is not recommended as monotherapy either. No efficacy data are available on amodiaquine monotherapy. Eritrea is already moving towards the implementation of ACT as the 1st line treatment. |
| Ethiopia | Chloroquine, sulfadoxine-pyrimethamine, and amodiaquine - all show high failure rates. The three drugs should not be used as monotherapy. Ethiopia seems to be planning already to change to ACT as 1st line treatment (using artemether-lumefrantrine (Coartem) for *P. falciparum*. The data on amodiaquine suggest that if this drug would not be an ideal partner-drug in artemisinin-based combinations. |
| Gambia | Both chloroquine and sulfadoxine-pyrimethamine show high failure rates. The two drugs should not be used as monotherapy. Gambia is recommended to change to ACT as 1st line treatment. More efficacy data on amodiaquine are required to know, whether this drug will be appropriate as partner-drug in artemisinin-based combinations. |

| | |
|---|---|
| Guinea | Both chloroquine and sulfadoxine-pyrimethamine show high failure rates. The two drugs should not be used as monotherapy. Guinea is recommended to change to ACT as 1st line treatment. More efficacy data on amodiaquine are required to know, to know whether this drug will be appropriate as partner-drug in artemisinin-based combinations.<br><br>Guinea has urgent need for support in antimalarial drug efficacy surveillance. It appears that UNICEF has recently made an agreement with Guinea to procure antimalarial drugs. This needs urgent follow up. |
| Haiti | No indications that Haiti should not continue the use of chloroquine as 1st line treatment. Haiti is in need of support for systematic antimalarial drug efficacy surveillance. |
| Madagascar | Chloroquine shows high failure rates, and so it should not be used as monotherapy. Relatively low failures rates with sulfadoxine-pyrimethamine; however, this drug is not recommended as mono-therapy either, but may be used for IPT in pregnancy. Madagascar is already moving towards the implementation of ACT as the 1st line treatment. Efficacy data on amodiaquine are required to know whether this drug will be appropriate as partner-drug in artemisinin-based combinations. |
| Malawi | High failure rates with sulfadoxine-pyrimethamine. This drug should not be used as monotherapy; but may perhaps be used for IPT in pregnancy. Malawi is recommended to change to ACT as the 1st line treatment. Efficacy data on possible partner-drugs are limited. |
| Mauritania | Chloroquine shows high failure rates, and should not therefore be used as monotherapy. Mauritania is recommended to change to ACT as the 1st line treatment. Efficacy data on other antimalarial drugs are not available. |
| Mozambique | High failure rates with chloroquine, and so it should not be used as monotherapy. Sulfadoxine-pyrimethamine should not be used as monotherapy either. The combination of amodiaquine + sulfadoxine-pyrimethamine shows high efficacy. This can be used but it is recommended to be in the context of an interim measure as the country prepares to change to ACT as 1st line treatment, as resistance may evolve rapidly. The interim combination therapy needs to be monitored closely. |
| Nepal | No efficacy data are available on chloroquine; however, it should not be used as mono-therapy, except for the treatment of *P. vivax*. Very high failure rates with sulfadoxine-pyrimethamine. Nepal is recommended to change to ACT as the 1st line treatment for *P. falciparum*. No efficacy data are available on possible partner-drugs to be used in an artemisinin-based combination. |
| Niger | Due to high failure rates with chloroquine, this drug should not be used as monotherapy. Efficacy data on other antimalarial drugs are not available, but sulfadoxine-pyrimethamine as monotherapy is not recommended as 1st line treatment either. Niger is recommended to change to ACT as the 1st line treatment. |

| | |
|---|---|
| Nigeria | No efficacy data are available on chloroquine; however, it should not be used as mono-therapy, except for the treatment of *P. vivax*. Very high failure rates with sulfadoxine-pyrimethamine. Nigeria is recommended to change to ACT as the 1st line treatment for *P. falciparum*. No efficacy data are available on possible partner-drugs to be used in an artemisinin-based combination. |
| Pakistan | Chloroquine, sulfadoxine-pyrimethamine, and amodiaquine all show high failure rates, and so none of them should be used as monotherapy in the treatment of *P. falciparum*. Pakistan is recommended to change to ACT as 1st line treatment for *P. falciparum*. Chloroquine could still be used for treatment of *P. Vivax*. The data on amodiaquine suggest that this drug will not be an ideal partner-drug in artemisinin-based combinations. Systematic surveillance of antimalarial drug efficacy is recommended, as well as technical support in general for antimalarial drug policy change. |
| Rwanda | Both chloroquine and sulfadoxine-pyrimethamine shows high failure rates as mono-therapy, and the combination of chloroquine + sulfadoxine-pyrimethamine as well. Amodiaquine may still be used for combination therapy. The combination of amodiaquine + sulfadoxine-pyrimethamine shows high efficacy and can still be used as an interim measure, implemented within the context of transitioning to ACT as 1st line treatment. Resistance against this interim combination therapy may evolve rapidly, why close monitoring of its efficacy is needed. |
| Senegal | Chloroquine shows high failure rates, and so should not be used as monotherapy. Sulfadoxine-pyrimethamine should not be used as monotherapy either. The combination of amodiaquine + sulfadoxine-pyrimethamine shows high efficacy and can still be used as an interim measure, implemented within the context of transitioning to ACT as first line treatment. Resistance against this interim combination therapy may rise rapidly, why close monitoring of its efficacy is needed. Presently, artemether-lumefantrine (Coartem) is used as 2nd line treatment. |
| Somalia | Due to high failure rates with chloroquine and with sulfadoxine-pyrimethamine, mono-therapy with these two drugs is not recommended. Chloroquine will only be appropriate for the treatment of *P. vivax*. Somalia is recommended to change to ACT as 1st line treatment. |
| Swaziland | Very limited drug efficacy data are available. Data from one study show moderate failure rates with chloroquine. Systematic antimalarial drug efficacy surveillance is recommended. The use of chloroquine as 1st line treatment does not seem to be an issue in Swaziland but this needs to be monitored. |
| Uganda | Both chloroquine and sulfadoxine-pyrimethamine show high failure rates and should not be used as monotherapy or in combination. Amodiaquine also shows high failure rates, and should therefore not be used as monotherapy. Uganda is recommended to change to ACT as 1st line treatment. A meeting of stakeholders is planned for June 2004 to adopt change of policy. Uganda has recently indicated artemether-lumefantrine (Coartem) as its 1st line treatment. |

**ANNEX 4**

## TOP TEN SERVICE INDICATORS OF PEOPLE REACHED
## (for routine reporting – generally every six months)

1. Number of people receiving antiretroviral therapy (ARVs)
2. Number of a. New smear-positive TB case detected; b. cases successfully treated and c. TB cases enrolled for multidrug-resistant treatment
3. Number of insecticide-treated bed nets (ITNs) distributed to people (or where appropriate, houses receiving Indoor Residual Spraying)
4. Number of people receiving antimalarial treatment (as per national policy)
5. Number of people counseled and tested for HIV, including provision of results
6. Number of HIV-positive pregnant women receiving a complete course of ARV prophylaxis to reduce mother-to-child transmission (PMTCT)
7. Number of condoms distributed to people
8. Number of people benefiting from community-based programmes (a. prevention b. orphan support c. care and support)
9. Number of people receiving treatment for infections associated with HIV (a. preventive therapy for TB/HIV b. STIs with counseling)
10. Number of service deliverers trained (a. health services b. peer & community programmes)

## TOP TEN OUTCOME/IMPACT INDICATORS
## (for medium term reporting: 1-5 years)

1. Percentage age 15-24 who are HIV infected (HIV prevalence)
2. Percentage still alive 12 months after initiation of ARV (reduced mortality)
3. Percentage of infants born to HIV-positive mothers who are HIV infected (reduced mother to child HIV transmission)
4. Percentage age 15-24 who had sex with more than one partner in last year
5. Primary abstinence (% never had sex, 15-19 year old). Secondary abstinence (% never had sex in the last year of those who ever had sex, in 15-24 year old)
6. Percentage age 15-24 with non-regular partners in the last year who reported consistent use of condoms with these partners
7. TB case detection rate and treatment success rate
8. Estimated all active TB cases per 100,000 population (TB prevalence rate)
9. Malaria-associated deaths (in high endemic areas, all-cause under-five mortality)
10. Incidence of clinical malaria cases (estimated and/or reported)

**Annex 5**

## Global Fund Funding (Rounds 1- 6)

| Rounds | Funding (US$) | Programmes | Countries |
|---|---|---|---|
| | | | |
| Round 1 | 565 million | 55 | 36 |
| Round 2 | 866 million | 98 | 73 |
| Round 3 | 623 million | 71 | 61 |
| Round 4 | 1,039 million | 72 | 52 |
| Round 5 | 770 million | | 60 |
| Round 6 | 846 million | | 63 |

**Annex 6**

## Global Fund Malaria Funding (Rounds 1- 6)

| Rounds | Funding (US$) | Countries |
|---|---|---|
| | | |
| Round 1 | 68 million | 12 |
| Round 2 | 242 million | 37 |
| Round 3 | 166 million | 20 |
| Round 4 | 417 million | 23 |
| Round 5 | 202 million | 26 |
| Round 6 | 202 million | 19 |

## Annex 7

### Summary Recommendations of the Institute of Medicine for treatment of malaria[244]

At the global level

Within 5 years, governments and international finance institutions should commit new funds of $300 million to $500 million per year to subsidize co-formulated ACTs for the entire global market to achieve end-user prices in the range of $0.10-$0.20, the current cost of chloroquine.

Artemisinin production should be stimulated in the short term by assuring and stabilising demand through funding of $10 million to $30 million per year from governments and international finance institutions. A centralized process for organising ACT procurement should be established.

Monotherapies for routine first-line treatment of falciparum malaria should be discouraged through a range of actions by the centralized procurement organisation and governments of countries where malaria is endemic, assisted by Roll Back Malaria (Geneva, Switzerland) and other global partners.

At the country level

All countries receiving subsidized ACTs should facilitate access to the drugs, especially among the poorest segments of society, and improve their effective use. Countries and funding organisations should support research towards those ends. Countries should be encouraged to perform intensive integrated control programmes in areas of low transmission where transmission maybe dramatically reduced or eliminated within a few years.

Monitoring, evaluation and research

All countries should be encouraged to monitor public and private drug distribution systems to assure that subsidized antimalarials reach their intended targets with at least the same degree of success as chloroquine. Technical and financial assistance should be made available to perform these tasks.

The following monitoring and surveillance activities should be made a routine part of every national malaria control plan: monitoring the effectiveness of drug regimens, treatment failures, and the emergence of resistant strains; and surveillance for adverse effects of antimalarial drugs. Both should be required as a condition of access to subsidized antimalarials.

The global research and development investment should quickly increase from $60 million to $80 million per year to guarantee the ongoing development of new antimalarials. One-half of this amount should go to Medicines for Malaria Venture (Geneva, Switzerland) from its regular funders, and the other half should be provided by the US government to the Walter Reed Army Institute of Research (Silver Spring, MD) and its public sector research partners.

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**244** Panosia, C.B. (2005). Economic Access to Drugs for Malaria

**Annex 8**

Groupe sanofi aventis
L'essentiel c'est la santé.

Paris, 6th July 2006

sanofi-aventis groupe

Dear partners,

In 2004 the international community was alerted to the risk of Artemisinin-based Combination Therapies (ACT) shortages expected from the urgent demand of endemic countries adopting the new anti-malaria treatment policies.
Industrial partners were requested to take action to prepare their production capacity for this challenge. Sanofi-aventis was one of the first companies to react, by launching several initiatives to make available large quantities of ACT at a "no profit-no loss" price. Efforts were made by many endemic countries to change their malaria policy (33 countries in Africa).

In spite of this, we face a major discrepancy between the official figures for ACT needs and the actual orders for ACTs. We have observed that:
- Several tenders never resulted in orders (e.g. Ghana)
- Purchase orders of some awarded tenders have been delayed. As an example, sanofi-aventis was chosen as the supplier of ACT for the Democratic Republic of Congo. A delivery program was established in December 2005. Two deliveries for an amount of 1,75 million treatments were made between December 2005 and March 2006. Unfortunately the scheduled delivery program was delayed and the 3rd delivery, for around one million treatments, is still pending, although drugs are available.
- Very few tenders have been issued for application in 2006 within the Global Fund program for artesunate + amodiaquine (AS+AQ) ACTs.

For sanofi aventis, this situation has several consequences:

1) ACT forecasts and production programs are collapsing. As a result, we have large quantities of finished products, produced as a buffer stock in anticipation of orders, which have reached less than 60% of their shelf-life. These stocks are as follows:

| | |
|---|---|
| AS+AQ co-blister adult formulation: | 169 000 treatments |
| AS+AQ co-blister child formulation: | 189 000 treatments |
| AS+AQ co-blister infant formulation: | 448 600 treatments |
| TOTAL | 806 600 treatments |

2) We placed orders with an artesunate producer 12 months ago and raw materials are in stock, a large part of which has already been transformed into artesunate tablets. Unless orders are passed rapidly, within a few months, 10 million artesunate tablets will have passed the 70% remaining shelf life required for tenders.

All in all, if the situation of orders does not change soon, the cost of manufacturing these ACTs and of their destruction is estimated at about 2 million Euros and represents 4 million wasted ACT treatments.



sanofi-aventis groupe
82 avenue Raspail 94255 Gentilly - Tél. : • 33 (0) 1 41 24 70 00 - Fax : • 33 (0) 1 41 24 75 53 - www.sanofi-aventis.com

At present, over 160000 AS+AQ co-blister treatments (infant, children and adult dosages) have reached less than 50% of remaining shelf life. To avoid the destruction of these essential drugs we have decided to donate them. Please let us know if you know of opportunities for donations.

Sanofi aventis is one of the few "Big Pharma" firms involved with you in the fight against malaria. We are fighting on multiple fronts, including a "no profit-no loss" ACT product offer, the development of a new fixed dose ACT combination and an active R&D pipeline. We wanted to share with you our disappointment at observing the lack of ACTs in the field at a time when we are considering destroying millions of treatments

Yours faithfully,

[redacted]

Dr Robert Sebbag
Vice President
Access to Medicines
Sanofi-aventis

sanofi aventis

**Annex 9**

## Lessons Learned from ACT reprogramming
## The case of Ghana

### The New Antimalaria Drug Policy in Ghana[245]

In 2003, the National Malaria Control Programme (NMCP) initiated a process to change the treatment of uncomplicated malaria in the country. This followed several anecdotal reports of reduced efficacy of chloroquine, the drug of choice for several years, and also evidence from detailed in vivo and in vitro surveillance work carried out by the Noguchi Memorial Institute for Medical Research and the NMCP. On the basis of the evidence provided from the surveillance data as well as other scientific reports available, the process of change was started. This involved extensive consultations with stakeholders across the nation organized by the NMCP. The outcome of the consultations was the decision to change from chloroquine to Artesunate-Amodiaquine combination as the first line choice for the treatment of uncomplicated malaria.

Thus, the decision to change from chloroquine to the use of a combination of Amodiaquine and Artesunate, besides being in line with current trends in the use of artemisinin-combination therapy (ACT) was informed by detailed scientific evidence based on work carried out in country as well as information from several stakeholders. Although the decision date was in June 2004, the start date for implementation of the new policy was set at January 2005. This was to allow the development of the necessary tools and materials for a successful launch. As part of the process of rolling out the new treatment policy, health workers were trained, information, education and communication messages on the new treatment to the general population. In addition, systems for adverse drug reaction monitoring and monitoring of the efficacy of treatment were instituted. Consultations with local manufacturers were also held.

During the latter half of 2005 reports of adverse drug reactions (ADRs) to the new drug treatment jolted public confidence in the new treatment and all the good work done by the NMCP and all involved has taken quite a bashing. Some commentators have even gone to the extent of suggesting that the NMCP had not done the necessary homework before recommending the change. As has been explained by the programme manager

[245] Based on report at the Global Fund meeting, Dakar, Senegal, March 2005.

and several others involved in the process, the decision to change had not been taken lightly. The reasons for change were overwhelming in that chloroquine efficacy had declined to less than 50% by 2003 (see Fig 1). In such a situation, it was unacceptable to treat a potentially fatal illness especially in children with chloroquine. More so, in most of the rural areas where contact with the health system is infrequent; it was essential that the benefits of such contacts were maximized by offering a better treatment drug than chloroquine.

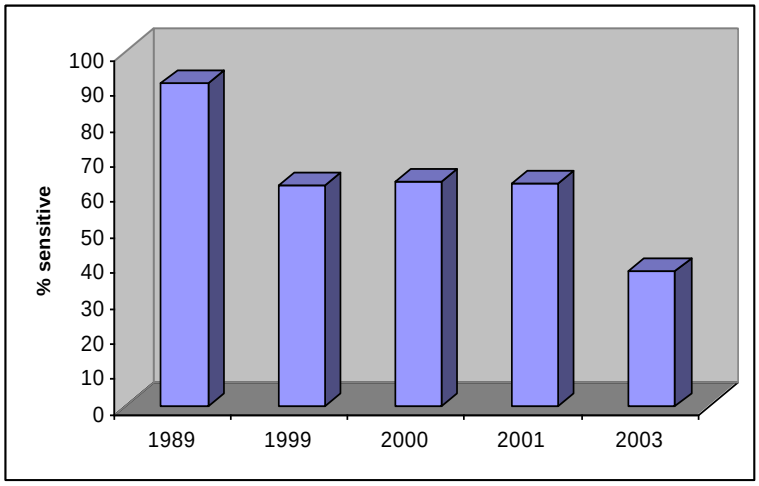
In view of this, it is quite important that the MOH, GHS and the NMCP do get to the bottom of the problem very quickly to bring out all the facts in order to restore the public's confidence in the new treatment. These ADRs need to be investigated as fully as possible and in a very objective and impartial manner. We will not be served in any way by uninformed comments on our airwaves. Unfortunately, these are tending to take over the decision-making process. We need to go back to basics and conduct a systematic evaluation of the ADRs to be able to pinpoint what the problem is. Although, the efficacy of the combination treatment may not be in doubt, the public perception of the drug especially in the urban areas has not been the best. In order to improve this, we need to provide scientific answers to counterbalance the half-truths we have been hearing and reading about of late.

Ghana pointed out the need to study the epidemiology of the disease in the whole population and be advised on any changes that might have occurred since the early descriptions were provided. In addition, the need to study the metabolism of the drug in our population because it seems a bit strange that although these are known possible effects of Amodiaquine, we are the only group of people reporting these ADRs to AQ, seeing that in more than 15 other endemic countries these problems have not occurred at the rate we have been reporting. This also brings into question the issue of the formulations we have on our market. We urgently need an independent analysis of all the various brands in the market to assure ourselves that we have the right quality of drugs on the market. These things have to be done with the utmost urgency because in the time being people would have to be treated of their malaria illness.

Finally, we should more than ever intensify our efforts at prevention. The basic fact of malaria is that if one is not bitten by mosquitoes, one will not get malaria! Although the risk of mosquito bite is largely unintentional, individuals can and should do something to reduce this risk. We should begin to think about constructing our dwelling places such

that we keep mosquitoes at bay. This will need the efforts of all especially those involved in the design and construction of our buildings. They should take up the challenge of designing simple houses suitable for our rural areas but essentially keeping mosquitoes out. Novel solutions as well as tried and tested solutions need to be employed. Above all, we will need governmental leadership in the battle against malaria, as a substantial reduction in the incidence of the disease will lead to substantial increases in economic benefits.

**Fig. 1. Parasitological Responses to Chloroquine 1989 - 2003**

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## CHANGING ANTI-MALARIA DRUG POLICY FOR GHANA: THE RATIONALE AND PROCESS

When chloroquine was produced many years ago, a major milestone in the fight against malaria was reached. Unfortunately, since 1998, both clinical and other evidence in Ghana showed conclusively that chloroquine is no more effective to be used as the first line drug in the treatment of uncomplicated malaria due to increasing resistance of the malaria parasite to the drug. Studies conducted by Noguchi Memorial Institute for Medical Research (NMIMR) in various sentinel sites spread across the country showed that clinical resistance levels to chloroquine ranged from 13%-34% and parasitological resistance levels of 21.7% - 49% using standard WHO protocol. Other studies done in Korle-Bu confirmed the high resistance levels to chloroquine.

The general guideline for change proposed by W.H.O. is as follows:

| **RESISTANCE LEVEL** | **PERIOD** | **ACTIONS TO BE TAKEN** |
|---|---|---|
| Less than 5%. | Grace | • There is not much urgency at this stage<br>• Build consensus on further data collection on epidemiological, social and health systems for monitoring purposes. |
| 6%-15% | Alert | • Mechanism for the process of change must be set up including timing of policy change |
| 16%-24% | Action | • Activities for policy change defined during the Alert Period must commence<br>• Potential drug alternatives must be evaluated. |
| **> 25%** | **CHANGE** | • Change should be affected within the shortest possible time. |

WHO Recommended Alternatives to Chloroquine/Monotherapies

WHO recommends that treatment policies for malaria in all countries experiencing resistance to monotherapies should be combination therapies, preferably those containing an artemisinin derivative (Artemisinin-based combination therapy-ACT). ACT gives rapid clinical and parasitological cure, reduces gametocyte carriage rate with no documented parasite resistance so far, and generally well tolerated with only a few documented adverse effects.

### Policy Change Process followed in Ghana

A major stakeholders' meeting was convened in August 2002 for dissemination and discussion of the research results. A task team was set up consisting of experts from NMIMR, Ghana Health Service, development partners, and Pharmaceutical Society of

Ghana, Ministry of Health, Department of Child Health, and Department of Community Health of University of Ghana Legon to come up with a new anti-malaria drug policy.

After almost two years, the task team developed a draft policy document after assessment of cost-effectiveness of various drug treatment combinations, potential for local production, potential side effects, cost to patients and health system, affordability and other factors. The therapeutic options recommended by WHO for first line anti-malaria treatment drug policy are as follows and an option appraisal was done on these:

- Artemether/lumefantrine (Coartem)
- Artesunate plus amodiaquine
- Artesunate plus sulfadoxine/pyrimethamine (in areas where SP efficacy remains high)
- Amodiaquine plus sulfadoxine/pyrimethamine (in areas where both drugs have high efficacy)
- Artesunate plus mefloquine (recommended and reserved for areas of low transmission).

The following criteria were used to decide on final choice: Efficacy, Compliance, Use for other interventions, Route of administration, Side effects, Cost effectiveness and Impact on local industry. The task team settled on Artesunate - Amodiaquine combination as the new first line drug for management of uncomplicated malaria.

**Cost comparison of adult treatment courses of available new combinations in relation to selected monotherapies**

| Antimalarial | Cost per adult treatment course |
|---|---|
| | US$ |
| CQ | 0.1 |
| SP | 0.1 |
| AQ | 0.2 |
| MQ | 1.6 |
| ART | 1.2 |
| Quinine | 1.35 |
| Coartem | 2.4 |
| ART/SP | 1.3 |
| **ART/Amod** | **1.4** |
| ART/MQ | 2.8 |

Source: RPM Plus/Rational Pharmaceutical Management Plus

**COST ANALYSIS OF DIFFERENT ACTS**

| ACT DRUG TYPE | National Costs | In % of Public budget | Per capita | In % PC |
|---|---|---|---|---|
| **Artesunate** | 5,828,160 | 5% | 0.3 | 1.5% |
| ***Artesunate - Amodiaquine*** | ***3,738,178*** | ***3%*** | ***0.2*** | ***1.0%*** |
| **Artesunate - Mefloquine** | 14,958,084 | 12% | 0.8 | 4.0% |
| **Arthemeter-Lumefantrine** | 6,488,155 | 5% | 0.3 | 1.7% |

### Why Artesunate-Amodiaquine was selected?

- It is very efficacious (97%); confirmed by NMIMR in Ghana.
- Has low side effects profile
- Has high parasite clearance rate
- Short treatment duration
- Safe in children
- Safe in pregnancy after first trimester
- Less expensive than almost all other alternatives to Chloroquine
- Can be produced and packaged locally

### Why Artesunate-SP was not selected?

The level of resistance of SP in Ghana, just as in most sub-Saharan African countries, is reasonably high and mounting. The WHO recommends the use of Artesunate-SP only in areas where resistance to SP is very low. The use of SP in Ghana has therefore been restricted for intermittent presumptive treatment for malaria in pregnancy as a preventive measure. As can be seen above, the cost differential between Artesunate-Amodiaquine and Artesunate-SP is insignificant on the international market (about USD1.4 vs. USD 1.3).

### Endorsement of New Policy

Another multi-sector stakeholder meeting was convened in May 2004 to discuss and endorse the policy document.

**After the Change**

- The new malaria policy has been incorporated into the Standard treatment Guidelines.
- Four multi-agency sub-committees, including representatives of the manufacturing sector, Food & Drug Board and private providers were then established with support from WHO and other technical agencies to develop detailed implementation plans on case management, procurement and distribution systems, communication aspects, and Monitoring & Evaluation (monitoring of efficacy, side-effects, quality etc.).
- Sensitisation seminars have been held for various stakeholders including health staff, local drug manufacturers, the press as well as the general public.
- Guidelines and training manuals based on new policy have been developed.
- Training of health staff has begun in earnest.
- With Global funding, 1,800,000 doses of Artesunate-Amodiaquine costing US$2,581,061 have been procured and in the central medical store ready for distribution. This represents *only 60% of the public health sector requirements. This means 40% of public health sector needs plus private sector needs, remain to be met.*
- So far, three local manufacturers have produced Artesunate-Amodiaquine and have been duly registered though they are yet to be pre-qualified by WHO. These are Danadams, Ernest Chemist and Kinapharma.
- IEC materials have been produced to educate general public on the new policy; all media channels will be used.
- NMIMR will continue to monitor the efficacy of the drugs,
- Food and Drugs Board and Pharmacovigilance unit will monitor the quality and side effects respectively.
- Food and Drugs Board is reclassifying the drug from class “C” to programme drug
- Operations research is ongoing to determine the feasibility of deploying the new drug combination for home-based care.

**Role of Government/Ghana Health Service**

- It is expected that the new drug will be heavily subsidised by government and health partners to meet the pocket of ordinary people. It is being proposed that the drugs sell at C3, 000 for full treatment course.
- When the National Health Insurance Scheme is fully operational, the treatment cost will be fully integrated into the scheme for all insured policyholders.

## ANNEX 10

| Interview Schedule | | |
|---|---|---|
| **Profile of Interviewee** | **Duration of Interview/Type** | **Year** |
| | | |
| FPM (Angola) | 30 minutes (Phone) | 2005-2006 |
| FPM (Benin) | 30 minutes (Phone) | 2005-2006 |
| FPM (Burkina Faso) | 30 minutes (Phone) | 2005-2006 |
| FPM (Cameroon) | 30 minutes (Phone) | 2005-2006 |
| FPM (Chad) | 30 minutes (Phone) | 2005-2006 |
| FPM (Comoros) | 30 minutes (Phone) | 2005-2006 |
| FPM (Democratic Republic of Congo) | 30 minutes (Phone) | 2005-2006 |
| FPM (Ethiopia) | 30 minutes (Phone) | 2005-2006 |
| FPM (Eritrea) | 30 minutes (Phone) | 2005-2006 |
| FPM (Ghana) | 30 minutes (Phone) | 2005-2006 |
| FPM (Gambia) | 30 minutes (Phone) | 2005-2006 |
| FPM (Guinea) | 30 minutes (Phone) | 2005-2006 |
| FPM (Indonesia) | 30 minutes (Phone) | 2005-2006 |
| FPM (Kenya) | 30 minutes (Phone) | 2005-2006 |
| FPM (Madagascar) | 30 minutes (Phone) | 2005-2006 |
| FPM (Malawi) | 30 minutes (Phone) | 2005-2006 |
| FPM (Mozambique) | 30 minutes (Phone) | 2005-2006 |
| FPM (Nepal) | 30 minutes (Phone) | 2005-2006 |
| FPM (Niger) | 30 minutes (Phone) | 2005-2006 |
| FPM (Nigeria) | 30 minutes (Phone) | 2005-2006 |
| FPM (Pakistan) | 30 minutes (Phone) | 2005-2006 |
| FPM (Rwanda) | 30 minutes (Phone) | 2005-2006 |
| FPM (Senegal) | 30 minutes (Phone) | 2005-2006 |
| FPM (Somalia) | 30 minutes (Phone) | 2005-2006 |
| FPM (Sudan North) | 30 minutes (Phone) | 2005-2006 |
| FPM (Sudan South) | 30 minutes (Phone) | 2005-2006 |
| FPM (Uganda) | 30 minutes (Phone) | 2005-2006 |
| | | |

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